EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

JOSEPH R. GOODWIN
MDL NO. 2:12-MD-02327 U.S. DISTRICT JUDGE

DEPOSITION OF DOROTHY KAMMERER-DOAK, M.D.
March 7, 2017

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

TVT General

APPEARANCES:

WAGSTAFF & CARTMELL LLP
By Christopher L. Schnieders, Esq.
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Appearing telephonically on behalf of Plaintiff.

BOWMAN AND BROOKE LLP
By Barry J. Koopmann, Esq.
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Appearing on behalf of Defendant.

Pursuant to Notice and the Federal Rules of Civil Procedure, the deposition of DOROTHY KAMMERER-DOAK, M.D. called by Plaintiff, was taken on Tuesday, March 7, 2017, commencing at 9:05 a.m., at 457 Mountain Village Boulevard, Telluride, Colorado, before Dianna L. Buckstein, Professional Shorthand Reporter and Notary Public within and for the State of Colorado.

I N D E X

P R O C E E D I N G S

(Exhibits 1 through 4 were marked.)

DOROTHY KAMMERER-DOAK, M.D. being first duly sworn in the above cause, was examined and testified as follows:

EXAMINATION

BY MR. SCHNIEDERS:

Q Good morning, Doctor. We are taking this deposition by phone, so I'm going to -- I would like you to bear with me. If we ever get to a point where you can't hear me or if I can't hear you, we might have to adjust the seating situation; but as long as you can hear me okay at this point, I think we're working okay.

Can you hear me?

A Yes.

Q Okay. Doctor, could you please state for the jury your full name.

A Dorothy Kammerer-Doak.

Q If I refer to you as Dr. Kammerer-Doak, is that okay?

A Yes.

Q Doctor, have you ever been deposed before?

A Yes.

Q On how many occasions have you been

deposed?

A Approximately six times.

Q Okay. We'll talk about that in a moment, but for the purposes of the deposition going well, I just wanted to briefly remind you of the ground rules that you probably already knew from those.

One, especially when I'm on the phone, it's important that you let me finish my question before you start your answer; is that fair?

A Yes.

Q Two, you're being -- your testimony is under oath today, and it's -- you've been sworn to tell the truth the same way as you would in front of the judge and jury.

You understand that, right?

A Yes.

Q Lastly, if I ask a question, especially over the phone, if I can't hear you or if it's an "uh-huh" or "huh-uh," I have a tough time understanding what that means and so does the court reporter; so I may ask you to repeat or to say, "Is that a 'yes'; is that a 'no'?" It's not intended to be rude. I just want to make sure we have a clear record, okay?

A Yes.

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Q Doctor, you understand that for the purposes of this deposition, you are here today to talk about an expert report that you have rendered in the Ethicon TVT litigation.
Do you understand that?
A Yes.
Q And it's your intention today to offer opinions with regard to the TVT device; is that right?
A Please repeat that.
Q It's your intention as we sit here today to offer opinions with regard to the TVT device that's manufactured by Ethicon, correct?
(Reporter requested clarification.)
Q (By Mr. Schnieders) -- manufactured by Ethicon, correct?
A Yes.
Q Okay. Now, as far as the other depositions that you've offered, Doctor, you said that you've been deposed on six occasions that you can recall; is that right?
A Approximately. I didn't count them out.
Q Okay.
A It could be -- it's somewhere between 6 and 10.

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Q Have any of those depositions occurred in the last five years?
A Yes.
Q And do you keep a list of your testimony that you've offered anywhere?
A No.
Q Did counsel before this deposition at any point ask you for a list of your dep -- over the last five years?
(Reporter requested clarification.)
A Sorry. Just someone just opened the door. Can you please repeat that?
Q (By Mr. Schnieders) Are you having a tough time hearing me, because I'm right in front of my phone.
A Yes. Let me see if I can turn this phone up any more. Okay.
Q Is that -- hopefully that's better. I'm not sure if it's going up or not. We'll see. I will try to keep my voice up and see what we can do here, okay?
A Okay.
Q Doctor, at any point prior to rendering your expert report, did counsel for Ethicon ask you to compile a list of all the depositions that you had given over the past five years?
A No.
Q Okay. And you never made a list like that?
A I have not.
Q Okay.
MR. SCHNIEDERS: Barry, I ask pursuant to civil procedure rules that you provide a list as soon as possible of those depositions, okay?
MR. KOOPMANN: I think that she hasn't been deposed as an expert witness in the last four years, and she said that in her general report, if I'm not mistaken.
MR. SCHNIEDERS: Well, if that's the case, we'll find out, I guess, here.
A No. I have not been deposed as an expert witness in the past four years.
Q (By Mr. Schnieders) Have you ever offered expert testimony?
A I was deposed as an expert witness about 10 or 11 years ago.
Q Okay. And what was that with regard to?
A It was with regard to an obstetrical anal sphincter laceration.
Q Were you offering testimony on behalf of a party in that case?

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A I was the plaintiff's expert.
Q Okay. And was that a medical malpractice case?
A Yes, it was.
Q Did you ever give trial testimony in that case?
A I did not.
Q Are you aware of what the resolution of that case was?
A I am not.
Q Now, with regard to the depositions that have occurred more recently, what has been the subject matter of those depositions?
A A fact witness.
Q Okay. Have they all been medical malpractice cases where you were a treating physician?
A Some have been where I was a treating physician, and the others have been -- and another one was -- I'm trying to figure how to best describe it. I wasn't the treating physician. I was defending another physician kind of as a character witness and to testify to her surgical skills as she had assisted me.
Q And what kind of physician was that

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physician?
A A gynecological physician.
Q And what was the subject surgery in that case?
A Say that again.
Q What was the subject surgery in that case?
A So she was assisting a GYN oncologist on a radical cancer surgery case that was laparoscopic. The surgeries that she's assisted me on were both laparoscopic gynecological cases and vaginal urogynecological cases.
Q Okay. With regards to any of these cases where you testified as a fact witness, did they involve transvaginal mesh?
A In one case she did have a sling placed, but that was not what the suit was about.
Q Okay. What was the suit about?
A She had developed a pelvic hematoma following a hysterectomy that was performed vaginally in a prolapse repair.
Q And if you can recall, where was that case filed?
A It was filed in New Mexico.
Q Do you know if it was filed in state court or in federal court?

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A I don't have any idea.
Q Okay. And that's fair. And, again, if we get to anything where you just don't know the answer or are not sure, that's what I want you to say. I don't want you to guess at anything.
You understand that the litigation we are here today regarding is in federal court in West Virginia.
Did you know that?
A Yes.
Q Okay.
THE DEPONENT: We're having a really hard time hearing you, Mr. Schnieders, and we're going to go downstairs and see if they can give us a better phone.
(Recess from 9:13 a.m. to 9:19 a.m.)
Q (By Mr. Schnieders) We're back on the record, Doctor. We were talking a bit about your deposition that you had offered in the past, and I think we established that all the depositions in the last four to five years were related to fact witness testimony in medical malpractice cases; is that right?
A Yes.
Q And I think we also established that the

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only case that involved transvaginal mesh product was actually about something else beyond that, and you didn't offer any testimony with regards to the mesh; is that right?
A We did talk about the sling in the case, but the case was not about the sling itself.
Q Got it. Okay. Doctor, I understand that we've brought -- you've brought some binders and other materials with you here today; is that right?
A Yes.
Q Okay. Can you tell us for the record what you brought with you?
A So I have a binder with my general TVT report, and the literature that was used to compile this. I also have a supplemental general reliance list in addition to the materials referenced in the report.
I have another binder that contains some of the key literature that was reviewed in the preparation. And I also have a binder that's labeled Stress Urinary Incontinence Mesh Documents Binder 1 that contains some company memos as well as other articles.
Q Okay. A couple things there, Doctor. You said something about a supplemental reliance list.

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Is there an additional reliance list to what you issued with your general report?
A I didn't finish my answer. I'm sorry.
Q Sorry about that.
A No. I also have two disks that contain all of the information. They're not disks, they're sticks. I have a copy of my invoice, as well as the e-mails. And I also have some articles that are in addition to what's in my original list.
Q Okay. Are you finished now, Doctor? I don't want to cut you off.
A I'm sorry. No. It's difficult when we're not face-to-face. Yes, I'm finished. Thank you.
Q No problem. So -- and you might have answered my question there with that last binder. It sounds like you've got a binder that has some materials in it that were not part of your original reliance list; is that fair?
A Yes.
Q Okay. And were those materials what is reflected in your supplemental reliance list?
A Some of these are in addition to what's in my supplemental reliance list.
Q Okay. Just for my benefit since I'm not looking at this binder, how many pages are we

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estimating are in that binder, how many studies?
A They're all -- they're loose. So I have 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 -- 18 documents.
Q Okay. And if I'm understanding right, not all 18 of those documents appear even on the supplemental reliance list; is that correct?
MR. KOOPMANN: Do you know the answer to that?
A I don't know.
Q (By Mr. Schnieders) Okay.
A Like for example, I know for sure some of them are not. One of the articles that I have is an article that I pulled regarding urethral erosion after synthetic and nonsynthetic pubo-vaginal slings, differences in management and continence outcomes. And I pulled that after reading Dr. Blaivas's deposition, where he had said he had never seen a urethral erosion after a pubo-vaginal sling. And so I pulled this where it showed that there are such a thing -- where there is such a thing.
Q When you say you read Dr. Blaivas's deposition, are you talking about his recent deposition he offered in the case specific context with regard to Crespin?

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A I'm not sure if it was that one or his general deposition, his general TVT, because I read both of those.
Q Okay. Well, his general deposition occurred well before you issued your general report.
Is that something you would have read before issuing your report?
A No. I read it recently.
Q Okay. And you recognize that that is on your list of reliance materials related to your TVT general report, right?
A What is?
Q Dr. Blaivas's deposition, his general deposition.
A Yes.
Q Okay. But it's your testimony today that you didn't read that prior to issuing your general report, right?
A Yes.
Q Okay. All right. I think I want to do it this way: So there's a thumb drive, as I understand, and I think there's also another thumb drive that's specific to Crespin.
MR. SCHNIEDERS: Is that right, Barry?
MR. KOOPMANN: Yes. There's two thumb

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drives containing general materials and one with just Crespin materials.
Q (By Mr. Schnieders) Okay. Now, the thumb drives that relate to general materials, would they encompass everything including what's in the binders there?
A Yes.
Q Okay.
MR. SCHNIEDERS: I'm going to mark those thumb drives as Exhibit 5, which is what I think we're up to. And I just ask that those be handled in the same way as previous thumb drives have with regard to making them exhibits, if you don't mind, Madam Court Reporter.
THE REPORTER: Okay.
(Exhibit 5 was marked.)
Q (By Mr. Schnieders) All right. Now, Doctor, you said that you pulled some additional materials, that are part of what I'm going to call the supplemental binder, yourself.
When did you pull those materials?
MR. KOOPMANN: Object to form. Go ahead.
A They were pulled over the past, I would say, two to three weeks.
Q (By Mr. Schnieders) Okay. And all of the

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other binders that contain materials that you brought here today, did you or your office actually put those binders together?
A The binders were put together by and given to me by Dr. Koopmann -- Mr. Koopmann, I'm sorry.
Q Okay. And so the materials that are in those binders were selected by Mr. Koopmann's office, correct?
A No. That's not correct. They were articles -- some of them were given to me or supplied by him, but a lot of them, in fact, most of them, are articles with which I am familiar or I asked to be pulled myself.
Most of the articles that are in the binders are ones that I have read before. Ones that are new to me are ones that are from journals that I don't typically access as a female pelvic medicine or reconstructive surgery specialist; and that would be, for example, the Journal of Urology, and then some of the European journals.
Q And I appreciate the clarification, but I want to make sure that we're tracking because that wasn't exactly my question.
It sounds like those binders don't have every single document that was part of your reliance

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materials; is that right?
A Yes.
Q Okay. So there were selections made from your reliance materials to put into those binders that you've brought here today, fair?
A Yes.
Q Who decided what those materials would be in those binders?
A It was based on my report that was generated.
Q And I'm not sure that I understand. You mean that they are the materials that were cited within the report itself?
A So in my general report, I have articles that I cited, and that is what is in the binder that contains my general report.
As far as the other two binders, those were given by Mr. Koopmann.
Q Okay. And those are selections of what ended up on the reliance list itself, fair?
A Yes.
Q And those selections were made by Mr. Koopmann's office?
MR. KOOPMANN: Object to form.
A Yes.

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Q (By Mr. Schnieders) All right. Doctor, you stated that you had some invoices there that you brought today; is that right?
A Yes.
Q I would like to mark those as Exhibit 6, please.
(Exhibit 6 was marked.)
(Discussion off the record.)
Q (By Mr. Schnieders) Doctor, how many pages am I looking at here in Exhibit 6?
A Two.
Q Can you tell me the dates of those invoices?
A So the first one says, Invoice for services November 2016; and the second one is from December, January, and February.
Q And that would track over December of 2016 through January and February of 2017?
A Correct.
Q Okay. And what's the total amount of those invoices in Exhibit 6?
A So from December through February, it's $16,886.45; and for November 2016, it's $4,434.50.
Q Okay. So approximately $20,000 of invoices that comprise Exhibit 6?

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A Yes.
Q Okay. The first invoice you said was November of 2016. Is that the first invoice that you have submitted in the Ethicon litigation?
A Yes, it is.
Q Okay. And I believe -- and correct me if I'm wrong -- that you also said there were some e-mails representing contact from Ethicon to you to begin the process of reviewing this case; is that right?
A That is correct.
Q Okay. I'd ask that those be marked as Exhibit 7, please.
(Exhibit 7 was marked.)
A And that's finished.
Q (By Mr. Schnieders) Thank you.
Doctor, when were you first contacted with regard to this case?
A It was probably sometime March or April of 2016.
Q Okay. And who contacted you initially?
A Mr. Koopmann.
Q And what -- what was the -- what was the request from Mr. Koopmann's office for you to look at?

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A So when he contacted me, he simply asked me if I would be amenable to being an expert witness for Johnson & Johnson.
Q Okay. And was that with regard to the TVT products; with regard to slings, generally; with regard to POP kits; or was there any specification?
A We discussed all of the above; and because I really haven't done a lot of the pelvic mesh kits -- in fact, none that were manufactured by Johnson & Johnson -- I said I was comfortable being an expert witness for the retropubic TVT sling.
Q Okay. Have you ever used Ethicon products for -- and -- strike that.
Have you ever used Ethicon vaginal mesh products?
A No, I have not.
Q Okay. So as we sit here today, you've never actually implanted a TVT?
A Well, no. You asked me about prolapse cases.
Q Well, and that's a fair distinction. Let me make it this way: So is there mesh in a sling?
A Yes. So I've implanted many Ethicon TVT retropubic slings.
Q Okay. And is the TVT retropubic sling the

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only Ethicon-manufactured mesh product that you used?
A Yes.
Q Okay. All right. So, Doctor, is there unbilled time that you have related to your general testimony that you're offering here today that has not been submitted yet?
A Starting from today -- starting from March 1st, yes, there's time.
Q Okay. And have you met with counsel for Ethicon over the past week at times?
A Yes, I have.
Q How many times?
A Once.
Q And for how long was that meeting?
A It was 7-1/2 hours.
Q And when did that occur?
A Yesterday.
Q Was that a face-to-face meeting?
A Yes.
Q Any other time that you've spent preparing for your deposition here today?
A Yes. We had a phone conversation.
Q Okay. What about time on your own? Is there any other time on your own that you've spent preparing for today's deposition?

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A In reviewing the documents that I will be discussing, yes.
Q Okay. And, for instance, with regard to the study that you've referenced in your supplemental binder, when did you go and find that?
A Within the past couple of weeks.
Q Okay. Any other materials that you have gone and found yourself that make up that supplemental binder?
A No, but there are -- let me amend that. There are things that I have asked for and have been supplied to me.
Q Okay. I think to make it -- so let me ask it this way: With regard to the binders that you've brought here today, did you make any notes or other highlights, anything like that in them?
A No, I did not.
Q So the binders themselves are just the printed-off pages of the materials on your reliance list as we discussed so far, right?
A Say that again, please.
Q Sure. It's a bad question.
The materials that are in the binders are just the printed-off pages of some of the materials on your reliance list, fair?

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A Correct.
Q Okay. So given that, I don't know that I need to mark the binders that are representative of materials that were on your original reliance list, but I do want to mark the binder that we are calling the supplemental binder.
MR. SCHNIEDERS: So if you wouldn't mind, I think that's Exhibit 8, please.
MR. KOOPMANN: Just so you know, Chris, that's not an actual binder; it's just a stack of paper.
MR. SCHNIEDERS: Okay. I think it's still probably -- we're going to get down to a lot of exhibits if we mark them all separately, so let's just call Exhibit 8 the supplemental materials.
MR. KOOPMANN: Okay.
(Exhibit 8 was marked.)
THE DEPONENT: Okay. That's done.
Q (By Mr. Schnieders) And lastly, just to make sure we're talking about the same stuff, I'm going to mark as Exhibit 9 the supplemental reliance list that you brought here today, Doctor.
(Exhibit 9 was marked.)
A That's finished.
Q (By Mr. Schnieders) Okay. And for my

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benefit since I'm on the phone, are there any materials that you have there that we haven't discussed at this point?
A No, there is not.
Q Okay. All right, Doctor. I'm going to ask you to turn to your CV if it's necessary, but we've marked it as Exhibit 2.
I'd like to talk a little bit about your background, okay?
A Okay.
Q All right. And, Doctor, you're currently in private practice; is that right?
A That is correct.
Q And where are you in private practice?
A In Albuquerque, New Mexico.
Q Okay. And tell me what your current practice is, meaning what do you do on a weekly basis.
A So the practice is focused on urogynecology. There are five health care providers there. I am a board-certified female pelvic medicine and reconstructive surgeon. And so what I see probably is about 60 to 70 percent urogyn, and then the remainder is general gynecology. And we focus on all types of issues in regards to the pelvic floor

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and problems in that area.
Q And are all of your colleagues urogynecologists as well?
A I have one other colleague that is board certified, and then the third person, who also specializes in pelvic floor disorders, is not board certified, but she has practiced a lot of it over the past 10 years and trained under me when I was training the residents at the University of New Mexico residency program.
Q Okay. And I think you referenced a couple of other colleagues. So what is their specialty?
A Gynecologists.
Q Okay. Sorry. Maybe I missed that.
And then you say that 60 to 70 percent of your practice is spent in urogynecological issues and the other 30 to 40 percent is spent in general gynecology; is that right?
A Yes.
Q So I want to take that percentage that's dealing with urogynecologic issues. Try to break down for me what that encompasses in your practice.
A So you mean what type of problems that it encompasses? Or what are you meaning by that?
Q Let's start with what you're treating and

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what the percentages are of that.
A Okay. So typical problems involve urinary and fecal incontinence, prolapse, other pelvic disorders, urological disorders that involve the pelvis such as interstitial cystitis or painful bladder syndrome --
(Reporter requested clarification.)
A -- bladder such as interstitial cystitis or painful bladder syndrome, chronic pelvic pain, pelvic floor muscle spasms, sexual dysfunction. I'm trying to think if there's any else. Oh, recurrent urinary tract infections.
So as long as it's in the pelvic area, I will evaluate that; but, for example, kidney stones or kidney issues, I don't deal with that.
I will work up persistent hematuria, including cystoscopy, but if an abnormality is found on cystoscopy such as a tumor, then I will refer those to the urologist to treat.
Q Okay. So you've mentioned urinary and fecal incontinence as part of that practice; is that correct?
A Yes.
Q Okay. And what percentage of your urogynecologic practice would you say encompasses

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urinary and fecal incontinence?
A So fecal incontinence is less common. So, you know, that would be in the range of somewhere between 10 to 15 percent. And then urinary incontinence often goes hand in hand, meaning it coexists with prolapse, so it would be more than 50 percent would involve urinary incontinence.
Q Okay. And is there any way for you to break out based upon that answer the amount of your practice that's urogynecologically spent regarding prolapse?
A I'm thinking. So, again, it would be somewhere in the range of 40 to 50 percent because, again, these conditions often coexist.
Oh, the other thing I will evaluate and manage is voiding dysfunction as well. That's another problem that we evaluate.
Q So if I'm tracking right with you, Doctor, it sounds like somewhere just north of 50 percent of your urogynecological practice is spent on urinary incontinence, which oftentimes overlaps with your prolapse treatment, fair?
A Yes, or coexists with the prolapse and vice versa.
Q Currently, when you treat prolapse, what

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are you typically going to do to help a woman?
A So there are three main treatments of prolapse. The first is conservative, and that involves trying to minimize the progression of the prolapse; and it's performing Kegel exercises, avoiding prolong standing, heavy lifting, constipation; and, oftentimes, if a woman is post menopausal, giving them vaginal estrogen, which doesn't take the prolapse away, but it thickens the vaginal tissues and makes the irritation from the prolapse less.
Secondly, is the use of a pessary, which is a device that's placed inside of the vagina; and it can be managed by the patient herself, or it can be managed by a health care provider.
And then, lastly, there's surgery.
And so when I see a patient, I discuss all three of the options with them, and then we come up with an individualized plan based on their examination as well as the symptoms that they have.
Q And what are the surgical options that you would currently be offering patients under those scenarios?
A So mostly we do vaginal surgery for primary, nonrecurrent pelvic organ prolapse, and that

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is a native tissue repair that is performed vaginally. So if a woman has a uterus in situ, we do a vaginal hysterectomy, and then we resuspend the top of the vagina, the apex, to ligaments on either side of the rectum up by the tailbone area.

If there is a cystocele that is central, then that is repaired, again native tissue using sutures with an anterior repair. And if they have a rectocele that is distal or in the middle of the vagina, we do a posterior repair with perineorrhaphy.

If somebody has recurrent prolapse, meaning they've undergone a surgery previously and it's failed, then we talk about a mesh augmentation of that surgery, and that can be performed either vaginally or abdominally.

At this stage, I really don't perform any more vaginal mesh cases. They are all done either laparoscopically or robotically with the abdominal sacrocolpopexy.

Q And in the scenario that you have decided to use mesh augmentation, what mesh do you use?

A So I am not performing the abdominal sacrocolpopexies. I haven't performed any for the past eight to nine years.

Q Okay. So the last time that you did

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perform a mesh augmentation, what mesh did you use?

A PROLENE.

Q What is the reason that you are no longer performing those procedures?

A Because there's very few ladies that require the abdominal sacrocolpopexy; and in private practice, those surgeries take about five hours in my hands. And so I have referred them out: initially, to the University of New Mexico; and now to my partner, who does do them.

When I went into private practice, which was about 8-1/2, 9 years ago, I didn't have someone to assist me that was familiar with that procedure; and my specialty is the vaginal route; and there's not a lot of people in New Mexico who do those types of surgeries. So that is what I specialized in.

Q Okay. And are you aware of -- strike that.

If I heard you right, you said that currently in that type of a case you're referring those types of patients to one of your colleagues in your practice; is that correct?

A Yes.

Q And are you aware of what mesh is used by your colleague?

A I am not. I know she uses the Y-shaped

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mesh; but I have not assisted her on any of the cases, so I'm not sure what mesh she is using.

Q The PROLENE mesh that you discussed using in the past, is that something that's available to be used today?

A I don't know. I haven't researched that.

Q Are you offering any opinions here today regarding the safety and efficacy of mesh when used to augment a POP repair?

A No. I'm specifically here to discuss the TVT sling.

Q Prior to referring on a patient to your colleague for the potential mesh augmentation, do you have any sort of a risk-benefit discussion with that patient?

A Yes.

Q And tell me what that entails.

A So when I'm talking about a prolapse repair -- I just want to make that clear -- we're talking about somebody who has recurrent prolapse?

Q Yes.

A Okay. So I discuss with them that their choices for treatment are conservative pessary or surgery; and that because they failed a previous native tissue repair, to do another one more than

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likely would fail; and so a mesh-augmented repair is something to be considered. We talk about going through the abdomen, and going through the abdomen as compared to going vaginally has a higher risk simply because we are in the intra-abdominal cavity.

We also talk about because of being in the intra-abdominal cavity, there's higher risks of bleeding because of where the mesh is attached over the sacral area.

We then talk about the risks of using mesh over native tissue and that we have to balance out the risks, increased risks of surgery, which do include the mesh as well as the operative approach, to the benefit of an increased chance of success. With vaginal native tissue repair, the success is approximately 80 percent; and with the mesh-augmented repair, it's approximately 90 percent.

Using the mesh for abdominal sacrocolpopexy, there's an approximate 10 percent risk of a vaginal mesh exposure, the majority of which can be treated vaginally; but rarely an intra-abdominal approach to deal with the mesh issue will be necessary. And this is, again, for the abdominal approach for abdominal sacrocolpopexy.

Q Okay. And if I heard you right initially,

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Doctor, you always suggest that the primary surgery with regard to pelvic organ prolapse be a native tissue repair, correct?
A Currently, that's what I do, yes.
Q Okay. And how long has that been the case?
A For about the past three to four years.
Q Prior to that, did you suggest that mesh augmentation would be primary?
A Prior to that in selected cases as per suggestions by organizations such as the International Urogynecology Association and the American Urogynecological Society, I would discuss the use of mesh for primary repairs under special circumstances, such as women with poor connective tissue who had very severe prolapse or had very significant weakness of their pelvic floor muscles.
Q What has changed in the last three to four years that has made you decide that native tissue repair should be utilized as the primary augmentation first?
A The litigation issue. I still strongly believe that vaginal mesh augmentation is a very viable option, but I don't want to expose myself to possible litigation from using them.
Q Do you believe that mesh is the better

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alternative under those circumstances?
MR. KOOPMANN: Object to form.
A I believe it is a viable alternative and something that can be discussed with the patient, the risk and the benefit profile, and it's up to the patient and myself to decide what she would like based on that risk-benefit profile.
Again, going back to what I had said previously, when I counsel a patient who has recurrent prolapse, we discuss that a vaginal native tissue repair has a lower chance of success but has less risks; and a mesh-augmented repair, whether it's done vaginally or whether it's done abdominally, has a higher chance of success, but has more complications.
So they have to choose between higher chance of success versus the complications, which primarily would be the mesh complications with the vaginal route, and abdominally would include the abdominal approach.
Q (By Mr. Schnieders) Okay. And so we're all tracking, Doctor, if a device fails -- sorry. Strike that.
In other words, we're tracking with regard to success, you're saying that 80 percent of the time

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that native tissue repair will work, whereas your experience or read of the literature is that 90 percent of the time mesh augmentation will work?
A So when we classify -- I have to define what you mean by "work." So when we talk about 80 versus 90 percent for the vaginal repair, it doesn't mean that the patient has no prolapse. What it means is that the prolapse if it does reoccur is not symptomatic or bothersome and it is at or above the hymen; and that for the abdominal approach using mesh, that is at approximately 90 percent.
Q Okay.
A And if we talk about the vaginal approach with mesh augmentation, it's best studied; and I only used it -- or mainly use it in the anterior compartment. And that in randomized trials, again, the anterior augmentation with mesh, synthetic mesh, has a higher chance of success than a native tissue repair.
Q And if I understood your testimony correctly, your only reasoning for not offering mesh augmentation as the primary repair is due to concern over litigation, correct?
A Offering it primary repair for special cases where the prolapse is severe, meaning grade --

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advanced Grade 3 -- I'm sorry -- Stage 3 to Stage 4 with weak pelvic floor muscles or connective tissue disorder.
Q I'll strike that based upon nonresponsiveness.
Doctor, as I understand your testimony, your only reason for not offering mesh augmentation as a primary repair for pelvic organ prolapse is due to concern over litigation, correct?
MR. KOOPMANN: Object to the form.
A So going back to my previous answer, in those special circumstances, yes.
Q (By Mr. Schnieders) Now, what we've marked as Exhibit 2 here, Doctor, your curriculum vitae is -- it's listed at 2015.
Is this up to date?
A I'm looking at it. No. I have a few other publications.
Q Okay. Do you have a more current version of this CV?
A I do.
Q I'd ask that you provide that to counsel, and then --
MR. SCHNIEDERS: Barry, if you could provide that to me, I'd appreciate it.

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MR. KOOPMANN: Sure. We will.
Q (By Mr. Schnieders) Doctor, I'll ask that you just generally, then -- not based on this CV -- have you ever published any peer-reviewed literature regarding the TVT?
A I have not.
Q Okay. Have you ever published any peer review literature regarding suburethral slings?
A No.
Q Have you ever published any peer review literature regarding pelvic organ prolapse?
A So let me go back to that. I did recently publish -- and this is something that's not on there -- it was a survey of the practice patterns of the International Urogynecology Association members as to their practice patterns for the treatment of prolapse and stress urinary incontinence, and in that case -- I mean in that instant, I did report on the use of the suburethral slings.
Q Okay. A couple questions. Is that a peer review -- peer-reviewed publication we are discussing right now?
A Yes, it is. It's the International Urogynecology Journal.
Q Would that be the IUGA that we're talking

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about?
A No. It's IUGA (pronouncing).
Q Okay.
A I-U-G-A.
Q IUGA (pronouncing) or I-U-G-A. And is that a professional society that you belong to?
A Yes, it is.
Q And, in fact, Doctor, have you been a member of the research and development team for IUGA?
A Yes, I have.
Q Okay. What other professional societies are you currently a member of?
A The American Urogynecology Society.
Q Any others, Doctor? I don't want to jump on your answer if you've not completed it.
A No. I'm also a member of the American College of Obstetrics and Gynecology and the Greater Medical -- I'm sorry -- the Greater Albuquerque Medical Association and the Society of Gynecological Surgeons. I don't think I'm current on my dues yet this year for that one.
Q Okay. And as a general proposition, AUGS is what we often refer to as the American Urogynecologic Study, correct?
A Yes.

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Q And then ACOG, that's the American College you referred to, correct?
A Yes.
Q Okay. And are those the four societies, the current societies that you belong to?
A Yes.
Q Are you an officer in any of those societies?
A No.
Q Would you say that you're more involved with IUGA, or I-U-G-A, than the other societies?
A Yes.
Q Okay. Describe your involvement with IUGA for us.
A So for the past -- now I'm past-chairperson of the research and development committee. So prior to two thousand and -- well, my chairpersonship lasted for five years, and I completed that in 2016.
Q Okay. And what was the research and development committee of IUGA?
A Do you mean what were their functions?
Q Yeah. What is the function of that committee?
A So one of the main functions was to review research grant applications and then to award the

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grants based on the review by the entire committee.
We also did research projects, and then we also did some literature reviews and wrote summary articles about them.
Also developed a mentorship program to mentor less experienced researchers within IUGA as well as people in training such as fellows and residents. Helped to develop what's now an e-learning program.
Also, looked into the development of an international database. We revised the sexual function questionnaire, and I was -- I personally was in charge of the international translation and validation project, where that revised questionnaire was translated into multiple different languages and then validated.
That's a general overview.
Q Thank you. And that sexual function questionnaire, Doctor, was that something that was funded by IUGA?
A That revision project was, yes.
Q Okay. The initial development of the questionnaire, was that funded by IUGA?
A No, it was not.
Q Okay. What was that funded by?

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A I don't think it received any funding.
Q Okay.
A I mean, it was funded by the University of New Mexico when we -- you know, when we developed it. We might have had it -- I'm sorry. We might have had a grant from the clinical research group at the University of New Mexico, but I don't recall.
Q And, Doctor, with regard to the grants process that you mentioned where research and development committee would be in charge of awarding grants; is that right --
A Yes.
Q -- where did those grants come from?
A They came from IUGA.
Q Okay. And where did IUGA receive the funds for those grants?
A I'm not sure. I wasn't part of the executive committee, so I do not know where the funds came from.
Q Okay. All right. Backtracking a little bit on your publications, Doctor, because we've got several pages here, and then it sounds like there's some additional publications that you had since the 2015 version that we have as Exhibit 2.
I think we established that you have never

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published anything regarding transvaginal mesh; is that correct?
A Yes.
Q Okay. And that includes suburethral slings and POP kits, correct?
A Yes.
Q Have you ever published on stress urinary incontinence?
A Not specifically stress urinary incontinence, but I have published on sexual function in women before and after surgery for prolapse and incontinence, and I've published on sexual function in women with and without incontinence and prolapse.
Q Any other publications with regard to that topic?
A For stress incontinence, we also published on the use of the Burch procedure in obese women, whether or not there was increased complications.
Q Any other publication?
A About?
Q About the topic we're talking about, stress urinary incontinence.
A Not in peer-reviewed journals.
Q And then I believe that in the reliance list you have one article that regards cadaveric

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fascia lata; is that correct?
A Yes. I was just going to bring that up. So I have published on the use of cadaveric fascia lata and the suburethral sling procedures, and the association with the use of the cadaveric fascia lata and erosion or exposure into the vagina with the cadaveric fascia lata with both abdominal sacrocolpopexy as well as the suburethral sling.
Q Any other peer-reviewed publications that you've authored or been a co-author of that have bearing on your opinions here today?
A I'm just going to take a quick look at this.
So something that would also be part of my experience is the randomized trial that compared the anterior colporrhaphy Kelly-Kennedy plication to the Burch retropubic urethropexy. So that is something that I utilized in forming my opinions.
Q Okay. And that's fair. Anything else?
A So I have also authored -- but this is not a peer-reviewed journal -- the Surgical Treatment of General Stress Urinary Incontinence in the Female Patient.
Q Anything else, Doctor?
A So there's also another article here, which

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is Predictors of Urinary Tension after Pelvic Reconstructive Surgery and Stress Urinary Incontinence Surgery.
Q Any others?
A No.
Q Do you have any pending articles or research that you intend to publish in the next couple years regarding these topics?
A No, I do not.
Q Doctor, have you ever conducted a randomized controlled trial?
A Yes.
Q Okay. What randomized controlled trials have you conducted?
A So the one that I mentioned that compared the Burch retropubic urethropexy to the Kelly-Kennedy plication for the surgical treatment of stress urinary incontinence.
And then we also conducted a randomized trial that compared the surgical treatment of obstetrical anal sphincter laceration third and fourth degree.
And then we also conducted a randomized placebo-controlled trial that compared antibiotic to no antibiotic for the prevention of post-operative

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urinary tract infection in women undergoing suprapubic catheterization following prolapse and urinary incontinence surgery.
Q Have you ever formed --
A Wait.
Q -- a clinical trial --
A One more. I also performed --
Q Are you not finished, Doctor? I apologize.
A No, that's okay. I also -- we also performed a randomized trial, again, placebo controlled, evaluating postoperative pain relief following laparoscopic tubal sterilization using the Falope-Ring, and it was a comparison between the use of ketorolac; bupivacaine, a local anesthetic; and placebo.
Q Okay. Are you finished with your answer? I don't want to jump in.
A I am. I'm sorry. It's really hard because we're not face-to-face. I apologize.
Q I get it. So, Doctor, just to confirm, you've never performed a study on transvaginal mesh, fair?
A I have not.
Q You've never published anything related to transvaginal mesh, correct?

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A I have not.
Q And, Doctor, going back to what we were discussing briefly earlier with regard to mesh augmentation for pelvic organ prolapse, is the mesh used in that surgery the same type of mesh as that used in the TVT?
MR. KOOPMANN: Object to form.
A It's a polypropylene mesh. So in that regards, the TVT sling is a polypropylene mesh as well.
Q (By Mr. Schnieders) Sitting here today, do you know if the mesh that's used in a TVT sling is the same or different from the mesh that's used to repair pelvic organ prolapse?
A It's going to be different in that it's larger and the way that it is put together. For example, the Perigee has the arms that have a little -- for lack of a better word, I will say "button" -- and I put that in parentheses -- that has a suture attached to it.
So the mesh that I used for prolapse repair vaginally is different than the mesh that's used for the TVT sling.
Q But the mesh itself with regard to pore size and everything else that goes into that is the

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same mesh, isn't it, Doctor?
MR. KOOPMANN: Object to form.
A I would have to review the pore size of the Perigee mesh to be able to answer that for sure.
Q (By Mr. Schnieders) Sitting here today, you don't know the answer to that question?
A The pore size of the Perigee mesh? No, I do not.
Q Do you know if the mesh that's used in a TVT is the same as mesh used by other manufacturers in suburethral slings?
A It can't be the same -- in my understanding, it can't be the same otherwise because it's protected by patent laws. So there are going to be some differences based on how they develop the product.
Q Sitting here today, do you have any appreciation for the difference between the mesh used in a TVT and the mesh used for Boston Scientific's suburethral slings, for instance?
A Yes.
Q What are the differences?
A So the pore size of the TVT sling is approximately 1,379 microns, whereas the pore size for the Boston Scientific is approximately 1,200.

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They're both about -- the weight is -- they are both approximately 100 grams per meter squared. So they're very similar. There is also some slight differences as far as other characteristics of the mesh, but they're going to be very similar.
Q Okay. And same thing with regard to TVT mesh versus an American Medical Systems product.
Are they the same mesh or different?
A Well, they are composed of polypropylene, but there are going to be differences in their exact weight and other characteristics.
Q And --
A They're not exactly the same.
Q What are the differences between their weight, for instance?
A So with the other one that you described, I would have to look it up to tell you for sure what the different weights are.
Q And do you know the different weights of any of the Boston Scientific suburethral slings?
A Didn't I just talk about the Boston Scientific?
Q I don't recall you saying anything about the weight.
A I said it was 100 grams per meter squared.

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Q Okay. Are you familiar with the Bard midurethral slings?
A The only slings that I have used are the Johnson & Johnson and the Boston Scientific.
Q Okay.
A So I have not utilized the others.
Q But sitting here today, you would acknowledge that there are differences between the mesh used in Boston Scientific slings and the TVT slings, correct?
A Very minimal differences, but there are differences, yes.
Q Okay. And there are differences between the TVT sling and the mesh used in American Medical System slings, correct?
MR. KOOPMANN: Object to form.
A So, again, what I've said previously is that there are going to be slight variations in how the meshes are made, but they're all composed of polypropylene, and they are all around the same weight, and they have similar pore sizes.
Q (By Mr. Schnieders) So when you say "similar pore sizes," for instance, in the Monarc -- which I believe you've used before, correct?
A I've used several times; and I haven't used

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the Monarc in, I would say, eight or nine years.
Q Okay. So what's the pore size for the Monarc?
A Off the top of my head, I can't tell you the pore size of the Monarc. I know it is considered macroporous according to the Amid classification, but the exact pore size of Monarc, I can't tell you.
Q Okay. Well, I'm happy if you need to refer to your materials, you can go ahead and do that.
(The deponent is reviewing documents.)
Q (By Mr. Schnieders) And I apologize if I'm interrupting, but I assume you're looking through your materials right now; is that right?
A Yes.
(The deponent is reviewing documents.)
A So what is your question for me?
Q (By Mr. Schnieders) What is the pore size of the mesh used for the Monarc?
A Can you tell me who makes the Monarc?
Q Do you know who makes the Monarc, Doctor?
A No, I do not. When I use a device, I use the device based on the characteristics of the device, and not the company.
Q Okay. It's American Medical Systems.
A Pore size is 1,000 microns.

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Q And what are you looking at for that?
A The Moalli article.
Q Okay. And is that something that you considered in forming your opinions today?
A The Moalli article?
Q No. The pore size of the Monarc mesh.
A I'm not forming an opinion on the Monarc mesh. I'm forming an opinion on the TVT sling.
Q Is it fair to say that the pore size of the Monarc mesh did not factor into your opinion today, correct?
A Correct.
Q Okay. Same question with regard to Bard and their slings; for instance, the ALIGN. Are you aware of the pore size of the mesh used for the ALIGN?
A So looking at this article, it's 1,160 microns.
Q Okay. And until you looked at that article just now, that's not something you fully appreciated, fair?
MR. KOOPMANN: Object to form.
A It's not something that I researched or would have researched because I do not use that product.

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Q (By Mr. Schnieders) Okay. And so it's fair to say that the pore size of the mesh used in the ALIGN is not something that factored into your opinions here today, correct?
A Correct.
Q And I could go through the list, but I assume your answer is going to be the same. The pore size of any mesh used in a midurethral sling that was not the TVT is not something that's factored into your opinions, fair?
MR. KOOPMANN: Object to form.
A Can you repeat that, please.
Q (By Mr. Schnieders) Sure. Well, I'll ask it -- because there was an objection, I'll ask it this way: Doctor, when you formed your opinions with regard to the TVT that you're here to offer today, the only pore size that factored into those opinions was the pore size of the TVT mesh and none of the other suburethral slings, fair?
A So in forming my opinion about the TVT sling, I looked at the pore size and, again, based on the admin article, and so the pore size of the TVT sling is the optimal pore size. I did not look at the pore size of other slings in forming my opinion.
Q Because the pore size of the other meshes

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and other slings is irrelevant to your opinion, fair?
A Yes, because I'm not offering an opinion on the other slings, just on the TVT.
Q Okay. Doctor, we've marked as Exhibit 4 -- and we'll go here on a break in just one second because I think we've been going about an hour -- but marked as Exhibit 4, your expert report that you're offering regarding your general TVT opinions; is that correct?
A Yes, if you say so. Let me look to see which number it is. Yes, it is No. 4.
Q Okay. And is it fair to say that report that we've marked as Exhibit 4 encompasses all of your opinions with regard to the TVT that you're here today to offer?
A Yes.
Q All right.
MR. SCHNIEDERS: Why don't we -- why don't we take a quick break because I think we've been going for a little bit over an hour at this point.
MR. KOOPMANN: Okay.
(Recess from 10:22 a.m. to 10:32 a.m.)
Q (By Mr. Schnieders) All right, Doctor, we're back on the record after a short break.
Did you review any documents during the

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break?
A I did not.
Q Okay. Before the break, we were talking about your reliance list and your report, and I think we've already talked about your report and the fact that it encompasses all of your opinions, correct?
A Yes.
Q And I realize that you have a supplemental reliance list that we've marked as Exhibit 9. And then I believe there's also some additional materials that may not be reflected in that, that we've marked as Exhibit 8.
But between Exhibit 8 and Exhibit 9, have we -- do we have all of the documents that you're relying upon to make your opinions in this case?
A All the documents, yes.
Q Okay. And I'm assuming that you're saying it that way because you're also relying upon your experience, correct?
A Yes.
Q Anything else?
A Anything else?
Q That you're relying upon to make your opinions as we sit here today?
A Well, my experience and my training, I

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would say as well. In addition to that, my continuing medical education, which is not reflected in all of the materials that are here today, which includes mostly yearly attendance at AUGS, IUGA, and SGS, and listening to presentations about this subject matter. And so those may not all be in my supplemental list.
Q And so just so we're clear, there have been continuing medical education programs at AUGS, IUGA, and ACOG that you would have also attended with regard to transvaginal mesh?
A Well, SGS, yes. I didn't say ACOG.
Q I apologize.
A That's okay. I don't typically go to those meetings.
Q Okay. But there would have been continuing medical education regarding transvaginal mesh that you would have attended at IUGA, AUGS, and SGS, correct?
A Yes.
Q All right. Doctor, earlier we briefly mentioned a sexual function questionnaire that I believe you had a hand in creating; is that correct?
A Yes.
Q And can you tell me just briefly what that

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sexual function questionnaire is?
A So it's called the Pelvic Organ Prolapse in Urinary Incontinence Sexual Function Questionnaire, or PISQ for short, P-I-S-Q, and the long form contains 31 questions and it assesses sexual function, specifically in women with these pelvic floor disorders. There's also a short form that contains 12 questions.
Q Okay. And that's for use both in the instance of pelvic organ prolapse and in the instance of stress incontinence; is that correct?
A Urinary incontinence. So not just stress incontinence; in all forms of incontinence. It's also been validated for use in the general population as well.
Q Gotcha. Okay. And I appreciate the correction.
Is this a questionnaire that you use in your clinical practice?
A It's -- I use it -- we have used it mostly for research. So I do not use this specific questionnaire in my clinical practice.
Q Okay. When you're evaluating a woman for a sexual function or sexual disorder function, what do you use in your clinical practice?

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A So I have a questionnaire that I use that encompasses prolapse urinary incontinence and sexual function. And that questionnaire contains questions about -- that are taken from the PISQ. So, for example, it says: Are you sexually active? And the answer is yes and no. And if not, is it because you're without a partner? And then: How often does pain interfere with your sexual activity? How often does prolapse interfere with your sexual activity? And how often does urinary incontinence interfere with your sexual activity?

So what that questionnaire does is it opens up the discussion for me with the patient as to what is going on. And there is some research to back this up that -- and it's a questionnaire by Plouffe, P-l-o-u-f-f-e, that says that three simple questions: Are you sexually active? Are you having any problems? and, Are you having pain with intercourse? are as effective in opening up the discussion and dialog about sexual function as a full-length interview.

So that is why I have chosen to address sexual function problems in this way, and then talking to a woman more about it when a problem is identified.

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Q Thank you.

Doctor, sitting here today, this deposition is being conducted in Telluride, Colorado; is that correct?

A Yes.

Q Okay. And your private practice is in Albuquerque, right?

A Yes.

Q And so it begs the question: What brings us to Telluride for this deposition?

A So currently I'm living here and -- as of December the 17th -- and traveling to Albuquerque to work there.

Q Okay. So currently with your clinical practice, you are commuting to Albuquerque weekly?

A I go once a month for an entire week.

Q Okay. And then you'll see patients for an entire week and then go back to Telluride; is that right?

A Yes.

Q Okay. So currently your current practice is to see patients approximately one week every month; and that's when you see them, right?

A Yes.

Q Okay. And is that just representative of

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wanting to slow your practice down a bit?

A It's a long story. My husband was supposed to be transferred for his work to Los Angeles, and so we put our home on the market. And our home sold very quickly, much more quickly than we had thought. And in between the time that our house sold and it closed, he wasn't transferred to Los Angeles, but there's still the potential that he may be transferred to Los Angeles. So we didn't know what to do.

We had a home here in Telluride that is our retirement home. So we put everything into storage, and I'm currently in Albuquerque -- I mean currently in Telluride and commuting back to Albuquerque for the time being until I know what happens in the future.

Q And I appreciate that, and I don't want to get into your personal life; that's not my intention. I just basically want to know: Is it your intention to continue working full-time; or are you planning on some sort of a slowdown in your work, ultimately, when this is all cleared?

A So I am not sure what's happening at this point in time, but more than likely a slowdown.

Q Okay. All right. Doctor, I believe we've

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established previously that the suburethral sling that you use in practice currently is the TVT, correct?

A I am doing a TVT sling. I am not using the Johnson & Johnson currently.

Q Okay. What is the current sling that you use?

A The Boston Scientific.

Q And do you know which of the Boston Scientific slings you're using?

A Yes. It's the Advantage Fit.

Q Any particular reason you're using that sling and not a Johnson & Johnson product?

A It was a monetary decision by the hospital because it was cheaper for them to get the Advantage Fit than the TVT.

Q When is the last time that you utilized an Ethicon TVT yourself?

A It would have to be several years ago. I can't give you the exact date.

Q Do you have any estimate of the amount of Ethicon TVTs you've implanted?

A So I've implanted over 2,000 retropubic -- and I'm just going to use "TVT slings" to encompass both types, both manufacturers. And I would say

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about two-thirds of them, somewhere between one-half and two-thirds, would be the Ethicon product. And yeah, one-half to two-thirds.

Q And when did you first start regularly using suburethral mesh slings?

A So prior to the Hilton and Ward study, way back when, I did use some Gore-Tex slings. That would have been many years ago when I was at the University of New Mexico after I completed my fellowship.

And I stopped using those slings when it was discovered -- not discovered, but that the pore size -- it was microporous and it was multifilamentous, and there's the Weinberger and Ostergard article that stated -- that demonstrated there was a very high risk of complications. So I stopped using mesh for slings following that. So that would have been in probably mid-1990s.

I then started using -- we talk about synthetic slings because I did use some cadaveric fascia, and, you know, those -- I don't know if you would consider them mesh or not, but synthetic mesh I started using in 2004.

Q And just so we're tracking, I would not consider cadaveric to be mesh --

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A Perfect.

Q -- or synthetic to be mesh, okay?

A Okay.

Q So 2004. And what was it about 2004 that led you to begin using synthetic mesh?

A So there was -- I was very aware of the TVT sling and that, you know, the first publications were in the late 1990s, but I didn't start using it until the Hilton and Ward study came out that demonstrated -- which is a randomized controlled trial that compared the Burch retropubic urethropexy to --

(Reporter requested clarification.)

A -- randomized controlled trial that compared the Burch retropubic urethropexy to the TVT sling.

So the initial publication for that came out a couple of years before, but I waited to use the sling until the Hilton and Ward had the two-year follow-up data and continued to show the same results.

Q (By Mr.Schnieders) Okay. So, specifically, it was the publication of that study that led to you deciding to use synthetic mesh in slings, correct?

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A Yes. Well, the TVT sling because I had used the synthetic mesh for the Gore-Tex many years before, but had abandoned that because of the high risk of complications.

Q That's fair, and just so we're tracking again, when I'm talking about synthetic mesh, I'm talking about what we're here to talk about today, which is what is used in the TVT, the polypropylene, okay?

A Perfect. Okay.

Q And specific to polypropylene mesh, it would be the Hilton study that led you to begin to use polypropylene mesh in slings, correct?

A Yes.

Q Doctor, have you kept track of the number of either Boston Scientific or Ethicon slings that you've implanted?

A I have not.

Q Okay. And it follows that you -- since you have not kept track of them, you don't have any sense of the complication rates of those, do you?

MR. KOOPMANN: Object to form.

A So I don't have a database with respect to complications, but I'm in a fairly unique situation in that there's only myself and the university or my

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practice and the university in the entire state of New Mexico who are urogynecologists.

There are a few urologists out in the community, but they do not do a lot of female urology. And so a patient would have to travel far in order to see somebody else if they had a complication.

Q (By Mr. Schnieders) But, again, fair to say that you have not kept track of this in any systematic way, right?

A Correct.

Q Doctor, do you know the difference between mechanically cut mesh and laser cut mesh?

A What do you mean by "do I know the difference"?

Can you clarify what you mean by that.

Q Well, first of all, for the jury's benefit, what does it mean to be mechanically cut versus laser cut for mesh?

A So "mechanically cut" means it was cut using a machine, if as you were to say kind of like using a knife or a scissors. And laser is using a laser.

Q And for the purposes of your opinion that you're offering here today, is there any distinction

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to be made between whether mesh is cut by a laser or cut mechanically?
MR. KOOPMANN: Object to form.
A So there is no difference clinically in the mechanically cut versus the laser cut.
Q (By Mr. Schnieders) And is it your opinion that there is no difference with regard to risk vis-a-vis mechanically cut or machine cut -- or laser cut?
MR. KOOPMANN: Object to form.
A There are no clinical studies that show any difference in risk between laser cut versus mechanical cut.
Q (By Mr. Schnieders) Are there any studies that differentiate between laser cut and mechanically cut?
A So there is one randomized trial that compares the TVT, which is mechanical cut, to the TVT -- I believe it's ABBREVO -- that is laser cut.
Q And when you say that there are no studies that demonstrate a difference between laser cut and mechanically cut, is that the study you're specifically talking about?
A There are also multiple randomized controlled trials -- although we do not know if the

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TVT was laser cut or mechanical cut -- that have been published since the introduction of the laser cut. And there are no difference in those outcomes as compared to prior to the onset of the use of mechanical cut -- or I'm sorry, laser cut.
Q So it's fair to say that your opinion that laser cut has the same safety profile as mechanically cut is based upon the fact that in your read of the literature it's the same as it was before laser cut came out?
A Yes.
Q Any other basis to state that laser cut and mechanically cut are equivalent from a safety perspective?
A From a safety perspective, no.
Q Doctor, is there a single, long-term, randomized controlled trial for TVT with safety as a primary end point?
A Yes, there is.
Q Can you please tell me what that is.
A I believe it's by Angli -- Angliotti (pronounced).
Q Is that something that you reviewed in your --
A Yes.

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Q -- preparation for drafting your expert report here today?
A Yes.
Q And it's your testimony sitting here today that that clinical trial has safety as the primary end point?
A The -- I just pulled it here. Yeah, it's Angiotti, Angiotti (pronounced). And I'll read you from the --
MR. KOOPMANN: Angioli?
A Angioli. Sorry. I have to put my glasses on.
So it says: Measurements. This five-year study represents the extension of our original randomized trial, which was designed to assess the incidence of long-term complications (primary end point) and successes (secondary end point) for both techniques. And it's a randomized trial that compares the tension-free vaginal tape versus the transobturator suburethral tape.
Q (By Mr. Schnieders) Okay. So, again, you're stating that that study is a single, long-term, randomized controlled trial that had four TVTs that had safety as a primary end point?
A It's five-year follow-up.

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Q And what do you consider to be long-term?
A Five years and greater.
Q Okay. The TVT is designed to be permanent, correct?
A Yes.
Q And, typically, what's the age range of a woman that's receiving a TVT?
A So the median age is going to be in the 50s.
Q So best estimate, we're dealing with women that have at least 25 years left of life most likely, correct?
A Yes.
Q But the long-term, randomized controlled trial for TVT that has safety as a primary end point that you're able to point to is a five-year study, correct?
A There are studies with up to 17 years of follow-up; and while safety was not the primary end point, safety and adverse events were recorded.
Q The only single randomized controlled trial for TVT that you're able to point to with safety as a primary end point is the Angiotti (sic) study, correct?
A With safety as the primary end point, but

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all trials track adverse outcomes.
Q What's the significance of an end point, Doctor?
A Primary versus secondary?
Q Primary versus secondary, yes.
A So it is all based on how the study is designed and the power analysis. So in order to ensure that there is a difference or no difference between two different types of interventions, a power analysis is performed, and that tells you how many subjects are needed in each group to ensure that you don't have a Type II or a beta error which indicates that finding no difference is due to lack of enough patients in your study versus finding no difference when you have enough patients in the study.
And so a primary end point simply tells you that that study was based on that outcome to find that there was a difference or no difference.
Secondary outcomes are also tracked, and it doesn't mean they're no less important. The study just was not powered to find a difference in those secondary end points.
Q When you say "powered," for the jury's benefit, you mean it didn't have enough people in the study to track that, right?

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A No. It just means that the primary end point is -- that the number of patients in that study were recruited to answer that specific question.
Q So using your words, Doctor, the only study that was developed and recruited to answer the question of safety with regard to TVT is the Angiotti study that you're referring to, correct?
MR. KOOPMANN: Object to form.
A Looking at the TVT in comparison to other types of surgeries, yes.
Q (By Mr. Schnieders) Now, you referenced a moment ago a 17-year study.
Can you tell the jury which study you're referencing?
A That's the Ulmsten study.
Q The Ulmsten study. And do you know who Dr. Ulmsten is?
A Yes, I do. And it's not Ulmsten, it's actually Nilsson, because I believe Ulmsten had passed away when that was written.
Q And was Nilsson a colleague of Dr. Ulmsten?
A Yes.
Q Who is Dr. Ulmsten?
A He is one of the inventors of the TVT sling.

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Q And with regard to that 17-year study that you're referencing, have you performed a power analysis on that?
A It's not a randomized trial. It is a cohort study, so there is no power analysis that can be performed.
Q And what is the difference between a randomized clinical trial and a cohort study, for the jury's benefit?
A So a randomized trial is where participants are randomized by chance to undergo one treatment versus another, and then those treatments are compared head-to-head, so to speak.
A cohort study is where patients are simply followed forward in time.
Q And do you recall how many people -- or I'm sorry, how many -- strike that.
Do you recall how many women were involved in the study that you're referencing with the 17-year data?
A So the original cohort I believe had 50 women in it, and the 17-year follow-up I believe had somewhere between 35 and 40. I would have to pull it for me to be able to tell you the specific numbers.
Q Okay. Now, are you aware of any other

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studies that are long-term that are random -- I'm sorry, strike that.
Are you aware of any studies longer than five years that are randomized clinical trials assessing TVT?
A So randomized controlled trials with more than five years of follow-up.
Q Correct.
A I think at this point in time we just have five follow-up year data. With randomized controlled trials there's --
Q -- market?
A Pardon me?
Q How long has the TVT been on the market, Doctor?
A Since the mid 1990s. Late 1990s. I'm sorry.
Q Taking the randomized trials out of it, are there any long-term studies with more than five-year follow-up with TVT?
A I'm sorry. Can you repeat that?
Q Yes. Taking -- so I'm stepping back from clinical trials or randomized clinical trials.
A Uh-huh.
Q Are there any long-term studies that have

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more than five years of follow-up with regard to the Ethicon TVT?
A Yes. There's 10-year data, and there is also, I believe, 13-year data, and there's also like 11.5-year data.
Q Okay. And can you tell me what studies you're referencing when you mention those years?
A So I would have to turn to my little section here to be able to tell you that.
Q That's fine.
A So Tommaselli. I'm pulling my notebook here.
(The deponent is reviewing documents.)
A Tincello. And then there is another one that I can't tell you off the top of my head, which is from an Asian author that has 10-year follow-up.
Q (By Mr. Schnieders) Are we done, Doctor? I don't want to step on your answer, but it sounds like you might be finished.
A Yes. I know there's a couple others. I just can't tell you off the top of my head.
Q I'm happy for you to look at your report and reference them if you need to.
(The deponent is reviewing documents.)
Q (By Mr. Schnieders) And not to be rude.

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I'm just making sure you're looking through your report right now, Doctor.
A Yes. And I think it's in my supplementary thing, my supplementary list. So I know there's several more. I just don't have them off the top of my head. It's not listed in my report, so it's not readily available to me.
Q Okay. And it's fair to say that if something is in your supplemental reliance list, that it was something that you did not review or consider prior to issuing your report, fair?
MR. KOOPMANN: Object to form.
A No, that's not correct.
Q (By Mr. Schnieders) Okay. Well, your supplemental reliance list was only made available to me today, whereas your original report you provided a reliance list with it. So anything that's been added since the time of your report has not been reviewed and been a part of your opinions that you're offering in this case, correct?
MR. KOOPMANN: Object to form. It misstates the record.
A So just because it's not listed in my general report doesn't mean that I did not consider it.

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Q (By Mr. Schnieders) Okay. Well, here's what I need to know, then, Doctor, because this is my one time to depose you on these issues. So I think we established earlier that between the supplemental documents in that list that I was provided today that has been marked as Exhibit 9, additionally some other materials that are marked as Exhibit 8, and the materials that were provided with your reliance list and your actual report, which was issued on January 31st of 2017, that we had encompassed all of the documents that you were relying upon; is that not the case?
A So just to go back, I have a long list of TVT long-term studies that I can read to you. And I apologize that it wasn't readily at my fingertips, but I --
Q That's fair, Doctor, but I just ask that you answer my question before we do that.
A Okay. Repeat that for me, please.
MR. SCHNIEDERS: Could you read that back, please.
(Last question was read.)
Q (By Mr. Schnieders) Okay. All right. And then, Doctor, could you tell me what you're reading from to tell us what the long-term studies are that

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you are referencing?
A So I'm referencing the TVT Medical Literature Binder 1.
Q Okay. And in that binder, what are you reading from?
A I'm reading from TVT long-term studies. So there's the Ward and Hilton with five-year follow-up, which, you know, we've established you want something longer than that. There's Liapis, which is five- and seven-year follow-up. There's Olsson Long-term Efficacy of the TVT Procedure. There is -- I don't know how to pronounce it -- Heinonen, Heinonen (pronouncing), and I believe that has 10-year follow-up. There's Svenningsen, which is 10-year follow-up, and he has -- he or she has two publications. Serati, which is 10-year follow-up.
We've talked about the Angioli article, which is five-year follow-up. Aigmueller, which is 10-year follow-up. Cresswell. Schiotz, 10-year follow-up. Jelovsek, which I believe is five-year follow-up, and that's a randomized trial comparing the laparoscopic Burch to the TVT. Seven-year outcome from Song. Prien-Larsen, which I believe is 7 to 10 years. It's not listed in the title here. Holmgren. Li, seven-year follow-up. Song, 13 years

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follow-up.
I have to put my glasses on. I'm sorry.
Q That's okay.
A Shao, which is 57 months. It doesn't quite meet our criteria. Seven-year follow-up, Reich. Groutz, 10-year follow-up. Han. And then Costantini, which is 100-month follow-up.
Q And I think you're done with your answer; is that correct, Doctor?
A That is correct.
Q Okay.
A Go ahead.
Q No, Doctor, did you do an analysis of the studies that actually tracked long-term pain?
A So I'm looking at the study which -- whose primary outcome was looking at adverse events. So that one -- I read that one about pain. The other ones, I'm not sure how many of them tracked pain.
Q It's fair to say that you don't know how many studies include long-term pain as a data point, right?
A Correct. Looking at the meta-analysis, and so the randomized trials that were included, some of those randomized trials were included in the meta-analysis and did track pain.

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Q And you don't know how many of those tracked pain as postoperative pain versus long-term pain, meaning over six months, correct?
A I think it's pain at any end point. And lots of studies do specifically address whether the pain was more than six months or less than six months or more than six weeks or greater than six weeks.
Q Sitting here today, Doctor, are you able to name the studies that tracked pain, meaning over six months?
A So if we look at the meta-analysis -- and I would have to get out -- by Schimpf, that compiles the studies that reviewed pain.
Q And does it differentiate between the studies that tracked long-term pain versus postoperative pain?
A I believe it does.
Q Okay. So your testimony here today is that meta-analysis indicates which studies tracked long-term pain versus postoperative pain, correct?
A I'm going to look at it right now to be able to tell you.
(The deponent is reviewing a document.)
A So the Schimpf study just reports on dyspareunia for the retropubic obturator mini-sling

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and pubovaginal.
And in reading those results there, I can't tell you whether it was short-term or long-term, but the typical way in which a study would be conducted if they are reporting on dyspareunia, it's going to be long-term.
It's not going to be in the immediate postoperative period or in the short term. It's going to be as long as they followed those patients up. So the follow-up would be anywhere from one to however many years the patients were followed up. They're reporting on that last visit.
Q (By Mr. Schnieders) Doctor, you would agree with me that you're speculating as to whether or not that study is tracking long-term or postoperative dyspareunia, correct?
MR. KOOPMANN: Object to form.
A What I would say is that the -- in having conducted many randomized controlled trials, that you don't report on your findings that are short-term. You report on the last visit with the patient. So it's not speculative. It is what would be considered scientific protocol in reporting.
Q (By Mr. Schnieders) So I can be clear here, Doctor, what are you pointing to, to say that

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that study is telling you that it's tracking the long-term dyspareunia through the meta-analysis?
A What I am pointing to is the way in which scientific studies are conducted.
Q Okay. So you're saying that it would be unscientific to even report on short-term dyspareunia?
A No. I'm not saying that. What I'm saying is that when authors who conduct these studies report on, for example, rates of dyspareunia, they're going to report at the last follow-up visit.
Q And are you able to tell me when the last follow-up visit was for each of those studies for each of the individuals that reported dyspareunia?
A So I would have to pull each individual study that is cited and -- to be able to tell you that.
Q Okay. And absent pulling each of those studies and reviewing that, you can't tell me, correct?
A The -- from each of the individual studies, the follow-up range anywhere from 2 to -- I think one of the randomized trials has 10-year follow-up.
Q And I'm going to move to strike. That is nonresponsive. I'm going to ask my question again.

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Absent pulling each of those individual studies, you can't tell me what the final follow-up was for those cases reporting dyspareunia, fair?
A And I will say that these studies have, at the minimum, two years follow-up, and at the maximum, I believe, nine years follow-up. So they are going to range from 2 to 10 years follow-up.
Q Okay. And you're extrapolating the Schimpf study only reports on long-term dyspareunia; is that correct?
A I am saying that the Schimpf study is reporting on dyspareunia at the last follow-up visit.
Q And you know for a fact that the dyspareunia has been reported at the last follow-up visit in each of those studies because you have reviewed that in forming your opinions that you're offering right now, Doctor, correct?
A What I said was, I'm giving that opinion based on how these studies are reported, that when you report outcomes such as cure, you're going to report it at the last visit. You're not going to report that the patients -- you're not going to report that the patients were cured 90 percent at two years and have that be in the meta-analysis when there's a full five years of follow-up. You're going

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to report your five-year follow-up data. So at that last visit is when those complications or those outcomes are going to be reported.
Q So, Doctor, just so I'm clear, you're talking about a meta-analysis, correct?
A Correct.
Q And a meta-analysis is a grouping of many different studies, correct?
A Yes.
Q All of which have different protocols, correct?
A All of them are designed differently or they could be designed similarly, yes.
Q But they have their own distinct protocols, correct?
A Yes.
Q You're not aware of those protocols as you sit here today, correct?
MR. KOOPMANN: Object to form.
A In the meta-analysis, you are not aware of the protocols.
Q (By Mr. Schnieders) And a meta-analysis is not actually reporting any first-hand information; it's taking other information and grouping it, fair?
A It's taking information from all the

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studies, and they analyze each of the studies. They give different weights to the studies based on the design of the study, and then they group -- or I'm sorry, they statistically analyze the results and come up with data based on the information from all of the different studies.
Q But it's fair to say that the information -- for instance, the reporting of dyspareunia that we're referencing, comes from the actual studies themselves, correct?
A So the information of dyspareunia does come from multiple different studies, yes.
Q And so the information is only as good as what was reported within that study, correct?
A Yes.
Q Doctor, what's the best type of study?
A Randomized controlled trial.
Q And if we're talking about the hierarchy of studies, what would come next?
A So then you have cohort comparison studies, where groups are compared but they're not randomized, and that can be divided into those that are followed forward in time versus those that are followed backward in time.
And then, lastly, you have just plain ol'

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cohort studies that are not compared to anything or anybody to a different group. So it's a longitudinal study. And those can be retrospective cohort studies, or they can be prospective cohort studies.
Q And with regard to trials, the longer the data that you can obtain, the better off you are, correct?
A I'm not sure I understand the question. So are you saying that the longer-term follow-up is better than short-term follow-up?
Q Correct.
A So it depends on what you're looking at. If you look at cure rate, the longer follow-up is, the better. Same thing for complication rates. But as far as certain complications like perioperative complications, you are only going to assess those in the short term because they are associated with the surgery.
So it depends on, you know, what you're wanting to look at and what you're wanting to evaluate.
Q Sure. That's fair. But if we are looking at something like chronic pain following implantation of a TVT sling, you want long-term follow-up, correct?

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A Yes.
Q That data is going to be more important to you as a clinician than short-term follow-up, correct?
A That's not necessarily the case. And that's because just because a patient develops pain, it doesn't mean it's caused by, for example, a TVT sling. As a patient ages, there's multiple factors that can contribute to the development of pain; most specifically, degenerative joint disease.
A person who is 40 years old is unlikely to have pain from degenerative joint disease, but when they're in their 50s and 60s, women can develop pain that's due to degenerative joint disease. So the development of pain long-term is not necessarily caused by the sling procedure.
MR. SCHNIEDERS: Okay. And I'm going to object and move to strike as nonresponsive.
Q (By Mr. Schnieders) I didn't say anything about it being caused by TVT, Doctor. I'm asking about looking at the issue.
If you want to determine whether or not there is an association or a causal relationship between implantation of a device like the TVT sling and chronic pain, the longer-term trials are going to

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give you more information, correct?
A No. Because, again, my answer -- I don't mean to be nonresponsive, but my answer to that stands because just because a patient develops pain, there's no way to know whether or not it's caused by the TVT sling unless you examine a person individually who is complaining of that pain. So just simply assessing pain long-term in a patient who has had a sling, there's no way to determine whether or not that is due to the sling in and of itself.
Q What's epidemiology, Doctor?
A It is looking at -- oh, that's -- it's hard to define. So epidemiology is simply looking at what happens within a certain population.
Q And, Doctor, your opinion here today is that the TVT device is not defective as designed, correct?
A Yes.
Q Is it your opinion that the TVT device cannot cause chronic pain?
A The TVT sling, it's possible that it could cause pain, but it's unlikely; and the association of TVT sling to pain has not been established. If you look at pain in women who have undergone -- and, again, looking at the Schimpf article, if you look at

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dyspareunia, if you look at pain, is that the rates are either the same or lower in women who've had retropubic slings and who have undergone other types of anti-incontinence procedure, including the Burch and the pubovaginal sling.
So while it's possible, I think it's very unlikely.
Q And you're -- strike that.
In order to form that opinion, you're relying upon studies, correct?
A I'm relying on my personal experience with the use of a retropubic TVT sling in more than 1,000 cases and possibly up to 1,500 cases. I'm also relying on a biological plausibility of a sling that is 1 centimeter -- 1.1 centimeter wide and very thin and where it's located within the body.
Any surgery that's performed within the human body has the potential to cause pain, and with the TVT sling, because it's minimally invasive, and because there's minimal tissue dissection, the potential for causing pain, as evidenced by the studies and by my personal experience, is minimal.
Q And you've not tracked your complication rates with your own implants, correct?
A I see probably --

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Q Doctor, we're going to be here a long time if you don't just answer the questions.
You've not tracked the complication rates of your own patients when you've implanted TVT or sling devices, correct?
MR. KOOPMANN: Object to form.
A I see multiple patients on a daily basis. I see approximately 20 patients a day, and I've been doing this for more than 10 years. So I've seen thousands of women who've had slings. And I have not examined a single patient who has had pain attributable to her retropubic sling.
Q (By Mr. Schnieders) You've never examined a patient where you've attributed the pain to the device, correct?
A I have never examined a patient where there has been pain that is caused by the sling, that retropubic sling.
Q I'm not trying to mince words here, Doctor, but you're the one attributing where the pain is from, correct?
A I have never found a patient who's had pain from the sling.
Q Who did the examination in these instances that we're talking about?

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A Myself.
Q Okay. Was there anyone else in the room that was deciding whether or not the pain was from the sling?
A No.
Q Okay. So you have not attributed the pain in all of those instances to the sling, correct?
A As a physician and expert in pelvic surgery and someone who has examined multiple women, thousands of women who have pain, on a daily basis when I'm in practice evaluated women with pain, I have not found a single case where a retropubic pain -- a retropubic sling has caused pain. And, yes, that is my expert opinion by examining thousands of women with pain.
Q Thousands of women that have TVT devices implanted?
A With and without TVT slings. So whenever I see a patient, one of the things that gynecologists and specifically urogynecologists see a lot of is pelvic pain. So I have examined lots and lots of women who have pelvic pain, some of which have TVT slings and some which do not.
Q Well, clearly the women that don't have slings can't have pain attributable to the sling,

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fair?
A Absolutely.
Q So how many women would you estimate you've seen that have slings implanted that you have examined for pain?
A Excuse me. Not very many. Not pelvic pain. Not pain -- I mean, they have pain that's like at the apex of the vagina, but pain over the TVT sling site that are retropubic, none.
Q Going back to what you said a moment ago, Doctor, is it your testimony in this case that it is biologically impossible for the TVT sling to cause pelvic pain?
A No, I didn't say that. I said it's highly unlikely.
Q Well, you were the one that brought up the term "biologically possible," Doctor, so what did you mean by that?
A What I mean is, is that because of where the sling is located, that it's retropubic and that it is very small, that its chances of causing pain chronically is very low. But I also said anytime that you do surgery on a patient, regardless of whether it's a TVT sling or it's a pubovaginal sling or it's a Burch procedure or it's an anterior repair,

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any of those procedures can potentially cause pain; but the chances with the sling, because it is minimally invasive and because it's so small, that's what I'm talking about as far as the biological possibility.
When you make a large incision, when you do a lot of tissue dissection, you know, those are things that can be associated with the development of pain when those incisions especially are within the vagina. And when we talk about pain here, I'm talking more about dyspareunia as opposed to chronic pelvic pain.
Q Okay. Doctor, with regard to the Burch procedure, would you consider it to be a gold standard in curing women's stress incontinence?
A It is one of the gold standards for the surgical treatment of stress incontinence.
Q Would you also consider an autologous fascial sling to be a gold standard for the treatment of stress urinary incontinence?
A I think the pubovaginal sling has more risks than the Burch retropubic urethropexi, but it has a higher cure rate. So I would utilize the pubovaginal sling for a subset of patients, and I wouldn't use it as a first-line choice, whereas the

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Burch would be a first-line choice.
Q Okay. So with regard to the Burch, let's take that.
What are the risks of a Burch procedure?
A So the risks of the Burch procedure are failure to cure the incontinence; development of de novo urgency incontinence or overactive bladder; injury to the bladder -- or the pelvic organs, so it would be the bladder, the ureter, the urethra; retention; not being able to urinate on a prolonged or permanent basis; infection; bleeding complications.
If permanent suture is used, that suture could potentially erode into the bladder. That risk is very low.
There's risks if it's done through an incision of incisional complications, hernia, infection of the incision, wound seroma. Those are not common complications.
Uncommon complications would be nerve injury, scarring in the retropubic space.
But if I were to consent a patient I wouldn't list all of those, I would only list the most common complications, which are the first ones that I listed.

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Q Okay.
A I would also --
Q And with regard to a Burch, what failure rate would you opine would occur?
A I just want to add to my last answer, I would tell the patient while a serious complication is rare, any one of those serious complications could require surgery at a later date. The success rate for the Burch in the short term, five years and less, is approximately 80 to 90 percent, and with follow-up of approximately up to 20 years, the cure rate falls off to 50 to 60 percent.
Q Okay. All right. Now, going to a TVT-felt sling, which I'm speaking specifically about Ethicon's TVT, what are the risks of the TVT?
A The same as above, with the exceptions we don't have the risk of the wound complications from the abdominal incision. And there is a risk of the -- instead of it being permanent suture, it would be the mesh being exposed within the vagina, the urethra, or the bladder.
Q And what is the failure rate on a TVT, in your opinion?
A So based on my review of the literature, it is 80 to 90 percent and --

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MR. KOOPMANN: He asked about failure rate.
A Oh, I'm sorry. I thought success. Failure rate is 10 to 20 percent.
Q (By Mr. Schnieders) And is that based on the five-year results?
A It's based on 5- and the 10-year and then the 17-year. It's --
Q It's -- up to 17 years the success rate is still 80 to 90 percent with TVT?
A No. The longer-term studies is they're more in the 80 percent range.
Q You would agree that from an efficacy standpoint, the Burch procedure is equivalent to TVT, correct?
A In the short term, and by that I mean five years and less.
Q So let's talk about a "mesh erosion." What does that mean?
A So I prefer to use the term -- and that's the term that's probably used more -- is "exposure." So that means that when a vaginal exam is done, the mesh is exposed within the vagina --
Q Okay.
A -- instead of being covered by the vaginal mucosa.

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Q So whether it's called an "erosion" or an "exposure," what does that mean?
A Pardon me?
Q Whether we call it an "erosion" or an "exposure," what does it mean?
A What do you mean, "what does it mean"?
Q What is that? What is that complication? If you see that when a woman comes into your clinic, what does that mean?
A So just what I said, that I can see the mesh in the vagina and it's not covered by the vaginal skin.
Q Okay. Does that mean it's eroded through something to get there?
A It means it's exposed. So whether -- that's why we don't use the term "eroded" anymore.
Q "Exposure" and "erosion" are two different things, aren't they, Doctor?
A I don't believe so.
Q Doctor, is there a difference between a suture and a mesh?
A Well, a suture is a suture and mesh is mesh.
Q Okay. So is mesh much larger than a suture?

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A So the mesh in the sling is 1.1 centimeters wide, whereas a suture is going to be, obviously, much smaller, in millimeter size.
Q And are you aware if they're made out of the same exact materials or if there are differences?
A Well, it depends on what suture was utilized. So, you know, for permanent sutures, there's multiple different kinds that could be used for pubovaginal slings or for Burch's.
Q And there's also dissolving or nonpermanent sutures that can be used, too, correct?
A Yes, but we wouldn't be talking about those sutures being exposed within the vagina or within the bladder or within the urethra because they would dissolve. They are dissolvable sutures.
Q That's right. Is there a risk of infection from mesh?
A Yes. With any surgical procedure for urinary incontinence, there's always a risk of infection.
Q With the introduction of a foreign body like mesh, is the risk for infection higher than it would be with the Burch procedure?
A I don't believe there's any Level I evidence that shows that the risk of infection is

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higher.
Q And when you say "Level 1," are you talking about a randomized controlled trial?
A Yes.
Q Are you aware of any evidence that shows that the risk for infection is higher with regard to mesh than it is with the Burch procedure?
A No, because if you look at a Burch procedure, you're going to have to take into account incisional infection in addition to -- which are going to be much greater than with a sling -- a TVT sling procedure.
Q You would agree that when we're talking about mesh that's placed vaginally, that you don't want it to be stiff, correct?
A Well, I think that when you place a sling, you want the mesh material to not be -- you know, you want the Goldilocks principle. You don't want it to be too loose because then it's not going to do what it's intended to do, which is to treat stress incontinence. So you want the correct balance.
Q And you would agree that larger pore size is better than smaller pore size, correct?
MR. KOOPMANN: Object to form.
A So you want a pore size that allows the

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macrophages to infiltrate to decrease the risk of infection. So the larger the pore size -- so no, I don't agree with that statement.
Q (By Mr. Schnieders) You'd agree that mesh causes scar plate formation within the vagina, correct?
A No, I do not.
Q So there is no scar plate formed within the vagina with mesh?
A So as with any surgery, anytime you're making an incision anywhere, you're going to have the body's reaction to that, which is some type of a, quote, scar, end quote. But as far as a scar plate, no.
Q Does the body react to the mesh?
A So the body will grow into the sling mesh that is there, and it becomes incorporated into that body's tissue. There will be a reaction to it, but it is not something that causes a, quote, scar plate to form, end quote.
Q So it's your testimony as we sit here today, Doctor, that there is no scar plate formed based upon the introduction of mesh, correct?
A A scar plate, no.
Q Doctor, what is the incidence of mesh

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exposure with the TVT?
A It's approximately 2 to 3 percent.
Q Would you agree that it has been associated with erosion or exposure rates of 34 percent?
A So if you look at small studies, there may be some rates are that high, but if you look at the overall incidence, it's about 2-1/2 percent. So no, I would not agree with that statement.
Q All right. Doctor, I would like to mark as Exhibit 10 -- I think is what we're up to -- your article entitled Vaginal Erosion of Cadaveric Fascia Lata Following Abdominal Sacrocolpopexy and Suburethral Sling Urethropexy.
MR. SCHNIEDERS: Do you have that, Court Reporter?
MR. KOOPMANN: We'll grab it here in just one second.
(Exhibit 10 was marked.)
THE DEPONENT: Okay. We have it.
Q (By Mr. Schnieders) Okay. And, Doctor, if you could first look at the front page. This is the article we referenced earlier. This is actually on your list of reliance materials that you've authored, correct?
A Yes.

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Q And if you go to -- it's kind of a long article -- but if you go to the third page, where Discussion starts --
A Uh-huh.
Q -- and go down to the second paragraph, the third full sentence starts: Synthetic grafts are associated with erosion rates of up to 12 percent for abdominal sacrocolpopexy with erosion rate -- and with -- and 34 percent for suburethral sling urethropexy.
Do you see that?
A Yes.
Q Okay. This is an article that you authored, correct?
A Correct.
Q And you're identifying that suburethral sling urethropexies have been associated with erosion rates of up to 34 percent, correct?
A This is in 19 -- this article was published in, I believe, 1999, and the sling material that was utilized whose rates have been reported up to 34 percent are not the TVT sling. It is from the use of Gore-Tex and Marlex. It's not from the TVT sling. This is before TVT slings were being utilized.
Q So if you go to the study that you're

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citing there, the Iglesia study.
Do you see that?
A Yes.
Q And is that something that you reviewed and included on your list of materials for your expert report here?
A The Iglesia article from 1997?
Q Yes.
A I don't recall if I have. I don't think I did.
Q Okay. So sitting here today, you're not aware of mesh erosion rates of up to 34 percent with regard to TVT polypropylene mesh, correct?
MR. KOOPMANN: Object to form.
A So there may be an individual study that shows that, but that is the benefit of looking at a meta-analysis where there's thousands of patients.
You may have a study population of 50 patients, and 17 of those have a mesh erosion, but you don't know if the next 100 patients have no mesh erosion. So when you group patients together and you have larger numbers, that's going to give you a better idea of the incidence of mesh erosion than looking at a single isolated study.
Q (By Mr. Schnieders) Sure. And that goes

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to your issue of powering.
A That's not powering. That is the numbers that have that complication. Power is a completely different issue.
Q I disagree, Doctor, and you didn't let me finish my question.
A I apologize.
Q I let you finish your question -- your answer -- so let me get back to it.
A Sure. I'm sorry.
Q -- a randomized --
(All speaking simultaneously, and reporter requested clarification.)
Q (By Mr. Schnieders) Let me start over.
Doctor, getting back to the power issue, in order to demonstrate something in a randomized clinical trial, you need to have sufficient numbers in order to be powered to detect that, correct?
A Yes.
Q And you would agree that there are no randomized clinical trials that have been powered to detect long-term pelvic pain, correct?
A For the TVT sling?
Q Yes, ma'am.
A Yes.

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Q Okay. Doctor, you would agree that mesh erosion -- or using your term, because you said "erosion" in your study here -- but mesh erosion or exposure causes pain for the patient, correct?
A Can you ask that question again, please.
Q I'm going to use the term "erosion" because that's what you used --
A Sure.
Q -- in your study or in your article we just looked at.
You would agree that mesh erosion causes pain for the patient.
A It can, but not always. In fact, most exposures are asymptomatic.
Q You would agree that mesh erosion can cause chronic pain.
A It's possible.
Q You would agree that mesh erosion can cause a scar.
A No.
Q Just so I'm clear, if mesh erodes through, for instance, the urethra, it cannot cause a scar? It's not possible?
A Where are you talking about a scar formation? I mean, the whole -- when you have an

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exposure or erosion, there is no vaginal tissue there. It's going to cause an inflammatory reaction --
Q Doctor, is a scar an inflammatory reaction?
A I'm just thinking out loud. So there could be some scarring from an exposure, yes.
Q Do you agree that mesh erosion can cause pain during intercourse?
A It can cause pain to the partner if they feel the exposed part, yes.
Q And is it your testimony that mesh erosion cannot cause pain to a woman that actually experiences it during intercourse?
MR. KOOPMANN: Object to the form.
A I don't understand the question.
Q (By Mr. Schnieders) So you answered on behalf of the partner. So I'm asking the opposite question.
Can mesh exposure cause pain to a woman during intercourse?
A I guess it's possible.
MR. SCHNIEDERS: Okay. I am starting to get down to -- I'm at about 35 minutes, so I'm going to take a quick break, get my materials back together, and then we'll get started again, if that's

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all right.
MR. KOOPMANN: Okay.
(Recess from 11:47 a.m. to 11:56 a.m.)
(Exhibit 11 was marked.)
MR. SCHNIEDERS: We're back on the record after a quick break.
Q (By Mr. Schnieders) Doctor, did you review any documents over the break?
A I did not.
Q Doctor, would you agree that polypropylene mesh shrinks inside of a patient?
A Not to any clinically significant degree.
Q But it shrinks to what you would call subclinically significant degree, correct?
A The evidence that I've seen shows that it hasn't shrunk significantly.
Q Would you agree that polypropylene mesh can degrade inside of the human body?
A No, I do not.
Q Okay. Do you think it's possible that it degrades inside the human body?
A Not to any clinically significant degree. If we look at, for example, cadaveric fascia lata in explant, there's a significant degree of degradation, and that is associated with a significantly lower

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cure of stress incontinence pretty quickly with time.
When we look at the TVT sling with follow-up ranging from 10 to 17 years, while there is a -- maybe a slight decrease, there's no significant decrease. So based on this, there's no clinically significant degradation of TVT slings.
Q Doctor, you would agree that you cannot determine if there is degradation unless you actually remove mesh from the body, correct?
A You could have microscopic degradation possibly that's not clinically significant.
Q Doctor, you would agree that Ethicon did not design the TVT mesh to rope, correct?
A Yes.
Q Doctor, you would agree that Ethicon did not design the TVT mesh to curl, correct?
A It's not been designed to do that, no.
Q And you would agree that Ethicon did not design the TVT mesh to fray, correct?
A So I have seen pictures, and I've seen some internal memos that when the TVT sling was pulled or stretched beyond physiological parameters that there was some fraying, but not under clinical scenarios when implanted --
Q And I appreciate that but --

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(All speaking simultaneously, and reporter requested clarification.)
A -- for a sling procedure.
Q (By Mr. Schnieders) Doctor, I appreciate it, but I need you to answer my question. I'm not asking whether it does fray or it doesn't fray. I'm asking: You agree that Ethicon did not design the TVT mesh to fray, correct?
A It's not designed to fray, yes.
Q And you agree that Ethicon did not design the TVT mesh to lose particles, correct?
MR. KOOPMANN: Object to form.
A It's designed to treat stress urinary incontinence.
Q (By Mr. Schnieders) And part of that is not -- it's not designed to have loose particles, correct?
A If a particle were to be lost, a small piece, it would not change its primary design, which is to treat stress urinary incontinence.
Q Doctor, that's not my question. I'm not saying that you're telling me that there are clinical consequences of any of these things. I'm just asking whether it was designed to lose particles or not.
Was it designed to lose particles?

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A I believe it wouldn't be designed to lose particles, no.
Q Did Ethicon design the TVT mesh to shrink?
A It was studied to make sure there was no appreciable shrinkage before they brought it on the market. So no, it was not designed to shrink clinically significantly.
Q And you agree that Ethicon did not design TVT mesh to easily deform, correct?
MR. KOOPMANN: Object to form.
A So I don't know what you mean by "easily deform." One of the properties of the TVT sling is that it does have stretching capabilities, and that's been hypothesized to be a good thing because it may prevent a higher risk of erosion such as what was seen with other materials that were not as, quote, stretchy.
So, again, it goes back to that whole Goldilocks principle is you want it to deform to some degree, but not too much.
Q (By Mr. Schnieders) You would agree Ethicon did not design the TVT mesh to be stiff, correct?
A Again, it goes back to the principle is that it has to be somewhat stiff in order to provide

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a hammock of support underneath the urethra against which the urethra can be compressed closed with increases of abdominal pressure.

If it's, you know, too loose, then it's not going to serve the purpose for which it was intended, which is to treat stress incontinence.

Q And, Doctor, you would agree that if the TVT mesh were to rope or curl or fray or lose particles or shrink, regardless of whether or not there's a clinical impact, it was an unintended consequence, correct?

A I'm thinking about that. Can you repeat the question.

Q Doctor, you would agree that if the TVT mesh were to rope or curl or fray or lose particles or shrink, that regardless of whether or not there were clinical impacts, that it was an unintended consequence.

A Yes.

Q Doctor, have you ever heard the term "pelvic cripple"?

A Yes.

Q What does that mean?

A So it is someone who has issues with being unable to have vaginal intercourse, secondary to a

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tight, small vagina, usually related to scarring from multiple previous pelvic surgeries. It can also --

Q Doctor, have you treated any women that you considered to be pelvic cripples?

A I'm also going to say, it also can involve pain on some levels as well.

And yes, I have.

Q Do you have an estimate as to how many women you have treated that you consider to be pelvic cripples?

A So there's varying degrees of, quote, pelvic cripples, end quote. Either somebody who has pain with intercourse and cannot have it comfortably, if it falls into that category, versus somebody who has, you know, a very -- like I described before, which would be very severe. So in that category of "very severe," fortunately, it's not a lot of patients. Maybe -- I would say less than 50.

And as far as to lesser degrees of having a tight, small vagina, still able to have intercourse but with some pain, you know, probably in the 50 to 100 range.

Q Of those women, are you aware of any of them that had transvaginal mesh implanted?

A They've had mesh for prolapse repairs, but

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again, going back to my earlier statement about not having seen a woman like this who's had a retropubic TVT sling, I would say that.

Q So your testimony, just so I'm clear, is that none of the women that you considered to be pelvic cripples that you've treated had a mid-urethral sling, correct?

A In isolation. So they may have had a TVT sling, but they also had multiple prior pelvic surgeries with and without mesh; for example, multiple previous prolapse repairs that could have been done with mesh or without mesh. And those patients could have also had a TVT sling, but not just a simply TVT sling in isolation.

Q Okay. Doctor, the mesh -- the polypropylene mesh that's used in the TVT, are you aware if it is the same or different than the mesh that's used in Ethicon's POP kit?

A So I have not used the -- Ethicon's pelvic organ prolapse repair kits, so I cannot answer that question.

Q And you haven't reviewed any literature related to them, either?

A To the Ethicon products? No, I have not for prolapse -- for prolapse kits.

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Q Okay. Doctor, would you agree that doctors rely upon companies such as Ethicon to tell them whether or not the products that they manufacture are safe?

A You're saying do they rely on Ethicon to tell them if their product is safe or not?

Q Yes.

A So it's one of the things that a doctor can rely upon, but I think it's the responsibility of the physician who is performing the procedure to have all the information. And the company that makes that device is not going to have all that information.

The literature is a place that I look. I rely on continuing medical education, going to the courses with presentations on both randomized controlled trials as well as cohort studies that look at complications, that look at risks. And I rely on my colleagues as well as my own personal experience.

So the last place that I look is with the manufacturer themselves.

Q But you agree that doctors in general use that as part of their analysis as to whether a product is safe, correct?

A As part of their analysis, yes.

Q And you agree that patients should be

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warned of all significant risks that accompany a procedure for implantation of a medical device, correct?
MR. KOOPMANN: Object to form.
A So I agree that patients need to be informed of the risks that are commonly associated with that device.
Q (By Mr. Schnieders) That are clinically significant, correct?
A That are commonly associated with that device and clinically significant, yes.
Q Do you agree that a medical device company has the responsibility to warn doctors about significant or clinically significant risks associated with the implantation of its devices?
MR. KOOPMANN: Object to form.
A So the doctor has the responsibility when he or she is using that device to know the risks, and part of the information gathering of the risks will come from that company.
Q (By Mr. Schnieders) Doctor, are you aware of the legal responsibilities that a company has in making and designing its IFU?
A I am aware of the -- some of the regulations that are involved, yes.

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Q And are those on your reliance list?
A They are in the materials that I provided today.
Q So you just in the past couple of weeks since your supplemental reliance list have gone and looked at statutes and CFRs related to the IFU?
A Yes.
Q Fair to say you hadn't reviewed those at the time you authored your report, correct?
A Correct.
Q Fair to say that as of the time of your authorizing of this report, you were unaware of the legal responsibilities of what is supposed to be in an IFU, correct?
A Yes.
Q Doctor, you'd agree that if Ethicon knew that a 30 percent shrinkage rate and an association with pain was correlated with the TVT products, that that's something it should pass along to physicians, correct?
MR. KOOPMANN: Object to form, foundation.
A So there is no evidence that there is that type of shrinkage when utilized clinically.
Q (By Mr. Schnieders) If there was, is that something that Ethicon should pass along?

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A If there was clinical evidence of that amount of shrinkage, then that should be passed along. And by "clinical," I mean, if there was evidence when used in treating women with stress incontinence that that -- there was that amount of shrinkage, then that should be passed on.
However, the clinical data does not support that in that the chance of undergoing a sling revision for urinary tension is quite low. It plateaus. It does not increase with time. And if there was that amount of shrinkage, you should see an increased -- a significant increase in sling revision for retention, both at the incident as well as increasing with time, and we just don't see that.
Q Doctor, have you been provided any internal Ethicon documents relating a 30 percent shrinkage rate with a TVT?
A I believe that's from abdominal wall hernia repairs. I've seen that.
Q Abdominal wall hernia repairs with a TVT?
A No. With the use of PROLENE mesh and abdominal wall hernias. I have not seen any documents that shows a 30 percent shrinkage rate of the TVT sling.
Q Okay. And that's something that you would

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want to know as an expert that's opining in this case, correct?
MR. KOOPMANN: Object to form.
A So, again, an internal document of what possibly could happen in the lab is not where I would place weight in making my opinion. It's how the sling behaves when implanted and when utilized for the treatment of stress incontinence.
And in my review of the literature, as well as my experience with my patients, we do not see that type of shrinkage. Again, if we would, we would be doing a lot more sling revisions for retention, and we don't see that.
In the Nilsson study which has that long-term follow-up, all of the patients that did not have comorbidities had a normal post-void residual.
We also have ultrasound studies that show that there is no change in the position. There's not any shrinkage -- or any clinically significant shrinkage.
We also have the study by Mimi Lukacz and her colleagues from San Diego, which two years after implantation, there was no change in the Q-tip angle, or in the hypermobility of the ureterovesical junction, which, again, shows that there's no

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clinically significant shrinkage.
So that 30 percent, if it happens in the lab or happens in animal studies, doesn't translate into what happens in real life. And that's what I'm basing my expert opinion upon.
Q (By Mr. Schnieders) And, Doctor, this is not a controversial issue. You just want to know all the information, don't you? You want to be given the information that is present so you can make your opinion, correct?
MR. KOOPMANN: Object to form.
A So again, going back to what I just said --
Q (By Mr. Schnieders) Doctor, I don't have time for you to go on, on the same tangent.
I'm just asking: You want to have all the information available to be able to make your opinions so you can consider it, correct?
MR. KOOPMANN: Object to form.
A I don't agree with that based on what I just said.
Q (By Mr. Schnieders) Okay. You don't want to have all the information before you make your expert opinion, fair?
A So I can review that information, but what I place my weight upon is not the -- whether or not

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it happens in a laboratory situation. It's what happens in real life.
Q But if you haven't been provided with that information, you can't factor it in one way or the other, correct?
A I can totally factor it in because regardless of whether that happened in a laboratory situation, I'm still going to have that same opinion.
Q Okay. So you are sitting here today, Doctor, saying that your expert opinion would not change even if there was hypothetical information that you don't even know what it says?
MR. KOOPMANN: Object to form.
A I have seen documents, again, that there is shrinkage of polypropylene mesh by 30 to 40 percent; and that is -- again, is in laboratory situations; and I am basing my opinion on what happens in real life.
And I would absolutely take that into consideration, but if I had that information, it would not change my opinion because I'm basing my opinion on what happens in real life and not what happens in a laboratory.
Q (By Mr. Schnieders) When you formed your expert opinion in this case, Doctor, and you read the

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studies that you have referenced in your reliance materials, you factored out all of the suburethral slings that were not Ethicon TVT, correct?
A No, because a lot of the studies that -- the highest form of evidence is the meta-analysis. And so a lot of the studies for the meta-analysis that we looked at -- that I looked at contains slings other than the TVT sling, the Ethicon TVT slings. The majority are going to be the Ethicon TVT slings, but it's not -- but they're not all.
Q Okay. Fair to say as we sit here today that of the literature that you've considered, you can't identify how often it's dealing with a TVT product versus a different manufacturer's product, correct?
A No. I can identify because the majority of the studies that I've looked at that are individual are going to be the TVT sling. And then when you look at the meta-analysis, you know, I did read how many were TVT -- the retropubics were TVT versus the other -- and, again, the majority are going to be TVT versus the other manufacturers.
Q Okay. But despite the fact that the other suburethral slings have different mesh, you didn't factor those out in your considerations, correct?

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MR. KOOPMANN: Object to form.
A So say that again.
Q (By Mr. Schnieders) Despite the fact that there are other manufacturers' suburethral slings and that those slings have different mesh then the TVT product, you did not factor those out, correct?
A No, because in my report it does say, Retropubic slings like the TVT. So when we look at the meta-analysis, I did take that into consideration. And when you look at the long-term studies, those are all going to be -- for the most part, all going to be the TVT slings.
Q Doctor, are you -- we established previously that you're a member of IUGA, correct?
A Yes.
Q Did you know that IUGA has put out a mesh complication classification system?
A Yes.
Q It's the Haylen article, but I did not see that reflected in your reliance materials.
Is that something that you've read?
A I have read parts of it, yes.
Q Any particular reason why you didn't read it for your expert reports in this transvaginal mesh case?

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A Because I was focusing on the TVT sling, so I did not reference that in this case.
Q Okay. And that classification system deals with complications of the TVT sling amongst other meshes, correct?
A Yes.
Q Okay. But you agree that that's not something you considered in forming your opinions here today?
A That article?
Q Correct.
A I did consider it when I used the word "exposure" versus "erosion." That's what I'm basing using that terminology.
Q Sitting here today, Doctor, you haven't even fully read that article yet, have you?
A I probably read 90 percent of it, and --
(All speaking simultaneously, and reporter requested clarification.)
A And I would also say that one of the reasons why it's not referenced is because there's very -- it's not used in very much of the literature currently -- in the TVT literature.
Q (By Mr. Schnieders) But it's a guideline from IUGA, correct?

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A Yes.
Q And you reference other guidelines from IUGA, correct?
A In relationship to the use of the TVT sling.
Q Those are in your report, right?
A The other guidelines from IUGA with respect to the TVT sling, yes, as well as to training of pelvic surgeons.
Q And I actually looked at the training of pelvic surgeons.
Would it surprise you that dyspareunia doesn't appear in that document in any way, shape, or form?
A I think it talks about sexual dysfunction.
Q Because you're using that as the basis to say that all pelvic surgeons are aware of all of the risks that are in the current IFU for TVT today, correct?
A Yes.
Q Okay. And they were going back into the mid-2000s, correct?
A Yes.
Q Then why is it that the IFU has changed over time?

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A You'll have to ask Ethicon about that. I can hypothesize for you, but I can't tell you why the company changed the IFU.
Q Okay. You would agree that you're not able to opine as to what was in the IFU and why, correct?
A No. I can tell you that in the IFU what's required according to the federal guidelines is for adverse events and complications which are unique to that device, are not well known, should be placed in the IFU.
Q And we established before that you had not read those federal guidelines until after drafting your report, correct?
MR. KOOPMANN: Object to form.
A Correct.
Q (By Mr. Schnieders) Doctor, are you familiar with the Agnew article entitled Functional Outcomes Following Surgical Management of Pain Exposure or Extrusions Following a Suburethral Tape Insertion for Urinary Stress Incontinence?
It doesn't appear on your reliance list. That's why I ask.
A I would have to -- that does sound familiar. I'm looking at the supplemental list here. No, it's not on my list.

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Q Which means you didn't consider it for your report today, correct?
A Correct.
Q Same with if there are articles that are not in either your reliance list, your report, your supplemental reliance list, or Exhibit 8, you didn't consider them in forming your opinions, correct?
MR. KOOPMANN: Object to form.
A I'm sorry. When he says that, I lose my train of thought.
Can you please read that back for me.
Q (By Mr. Schnieders) Sure. And I can just ask it again.
If the -- with regard to the articles, if it's not -- or studies, if it's not in your expert report, your reliance list, your supplemental expert report, or your supplemental reliance list as Exhibit 9, or your materials in Exhibit 8, it's not something that you considered in forming your opinions, correct?
A Correct.
Q Doctor, you're not an expert in the design of the TVT, correct?
MR. KOOPMANN: Object to form.
A So I have utilized different devices in

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pelvic surgery for more than 20 years. So I would say I'm an expert in the -- their use.
Q (By Mr. Schnieders) Right. But as far as actually designing products, you've never designed anything for a device company, correct?
A I have not designed something for a device company, but I certainly have utilized or evaluated multiple devices. And in that sense, I'm an expert in what is used within the female pelvis as far as devices.
Q In your expert report, you say that a pore size is enough that one can see through the mesh easily, and it's sufficiently large to permit tissue ingrowth and permit entry of microfascias to clear material.
You would agree that that's a statement that you are making -- strike that.
Sorry. Strike that. I'm running out of time.
Doctor, what's the proper way to tension the TVT device?
A So that is something that is individual based on the patient. If you compare the TVT sling as -- to the pubovaginal sling, the traditional slings, those slings were placed under somewhat

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greater tension because they were tended to be used for, quote, rescue when people had real severe incontinence.
So the tension that's under the TVT sling should be minimal to tension free. And when the TVT sling is placed according to the original protocol developed by Ulmsten, he would fill the bladder to 300 milliliters and then have the patient cough and adjust the tension until the tension -- until the patient had only drops of urine.
And the way I train and the way I perform the TVT sling is in patients who have more severe incontinence, I follow the Ulmsten method, where I have the patient cough, or I will simulate a cough by pressing on her abdomen with 300 milliliters, and tighten the sling down until there's no leakage.
In women who do not have severe incontinence, then I will place it under minimal to no tension.
Q Do you believe that Ethicon is responsible to tell physicians how to properly tension its device?
A No, I don't believe Ethicon is responsible at all. Again, that's when you are treating stress incontinence surgically, whether it's with the Burch

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procedure, the pubovaginal sling, or with the TVT, it's somewhat of an art in how to tension it.
And just like I said, back when you tied down the Burch stitches, oftentimes you would tie them down as tightly as possible. But then we started to learn if you tied it down really tight, then they might have some degree of obstruction. So then we tied it down until we thought there was adequate support.
With the TVT sling, again, you want -- you have a way to kind of guide how tight to make the tension by the intraoperative stress test or placing under no tension at all with -- in patients who don't have significant incontinence.
And that is not something that Ethicon can teach. It's something that's learned through mentorship or through continuing medical education courses. And, you know, if it's a course that Ethicon sponsors, that's fine; but, you know, the way I learned was through mentorship and by reading the original report that Ulmsten wrote. And, again, any reasonable physician who is performing that surgery should know that.
Q Okay. And, Doctor, what does IFU stand for?

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A Oh, my brain.
Q Is it Instructions for Use?
A Thank you. Instructions for Use.
Q Okay. So, literally, the IFU are the instructions for use for the TVT, correct?
A Correct.
Q And they discuss how to tension the TVT device, correct?
A Yes, that's in there.
Q Okay. Do you agree that the strongest unmet need with a TVT is the ability to adjust tension both intraoperatively and postoperatively?
A No, I don't agree with that.
Q Do you believe that the ability to adjust tension both intraoperatively and postoperatively is maximal and there's no need to improve on that?
A Well, you can't adjust it postoperatively, but I'm not sure that it's an unmet need. You can't adjust tension on a Burch or an autologous pubovaginal sling, either.
In the operating room, you can certainly adjust the tension on the TVT sling just as I described.
Q Do you agree that there is not a consensus on the right size of the mesh used for SUI?

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MR. KOOPMANN: Object to form.
A So the right size -- you mean pore size?
Q (By Mr. Schnieders) No. The right -- the amount of mesh used.
A So the question is: Is the amount of mesh that -- "the size," you mean as far as whether it's 1 centimeter or 2 centimeters?
Q The amount of mesh used in a sling, Doctor.
A So I believe there is a consensus from many societies -- IUGA, AUGS, SUFU, a whole lot of other ones, that the TVT sling is considered to be, quote, the gold standard. And so that size of a mesh, I would think, would be a consensus.
The midurethral slings, the ones that are used now, are all in the range of 1 to 1.1 centimeters, so I believe --
Q Is that the --
A -- there is a consensus.
Q -- product that --
(All speaking simultaneously, and reporter requested clarification.)
Q (By Mr. Schnieders) Has Ethicon come up with a product that uses less mesh in a sling?
A So I know they've investigated the use of a mesh that was partially absorbable, but they weren't

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able -- in animal studies, there were some deficiencies in it, so they did not bring it onto the market because it was -- it didn't work in the animal models.
Q Doctor, you would agree that in order to limit mesh-related complications of exposure or erosion, that it's optimal to use the least amount of mesh necessary to achieve efficacy, correct?
A So the sling that we have now has a very low risk of mesh exposure, and it has a high rate of efficacy. So if there were any changes to that mesh, it may not work as well. And so I can't agree with that statement.
MR. KOOPMANN: Counsel, your three hours are up.
MR. SCHNIEDERS: Well, I'm going to make her answer that question again. She didn't answer it.
So read it back. And then that will be my last question.
(Last question was read.)
A And as I said, I don't agree with that statement because you have to -- you have to balance efficacy with risks of complications. And, again, we have a safety profile over a large number of years

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that shows very low risks of erosion with the mesh that we have currently.
MR. SCHNIEDERS: All right. Barry, you want to -- how long do you guys want to take in between depos?
MR. KOOPMANN: Well, I want to ask some follow-up questions first, and then maybe we'll take 45 minutes between the two, if that's all right.
MR. SCHNIEDERS: Sure.
MR. KOOPMANN: Okay.
EXAMINATION
BY MR. KOOPMANN:
Q Dr. Kammerer-Doak, I want to ask you some follow-up questions based on plaintiff's counsel's questioning.
You were asked earlier today about what sort of publications you had. And is it true that you've published on pubovaginal cadaveric fascial slings?
MR. SCHNIEDERS: Object to the form.
A Yes, I have.
Q (By Mr. Koopmann) Does your report that has been marked today as Exhibit 4 contain your opinions regarding the safety and efficacy of the TVT and the labeling for that device?

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A Yes.
Q And do you hold those opinions to a reasonable degree of medical certainty?
A I do.
Q And what are the bases for the opinions that you've provided here today?
A It's based on my review of the literature. It's based on my training as a resident and as a fellow. It's based on more than 20 years of experience as a specialist in pelvic floor surgery. It's based on continuing medical education at conferences that are specific for pelvic floor disorders, including the AUGS, IUGA, and SGS.
Q Would it also be based in part on your medical education --
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) -- medical school education?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) Are your opinions today based in part on your -- the research that you've done over the course of your career and the publications you've issued?
MR. SCHNIEDERS: Object to the form.

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A It's based on my research as well as my personal experience. And I hold kind of a unique situation. Even though I don't practice at a tertiary care center, because of the fact that the state of New Mexico has paucity of specialists, I have been referred patients from all over the state of New Mexico, as well as Northern Texas, Arizona, and Southern Colorado.

So I just don't see routine cases. I, again, function closer to a tertiary care center.

Q (By Mr. Koopmann) Do you practice evidence-based medicine?

A Yes, I do, to the --

MR. SCHNIEDERS: Form.

A -- best of my ability.

Q (By Mr. Koopmann) What does that mean?

A That means I look at the literature, and I base my practices as best I can on the evidence that's out there. For example, I did not start using the TVT sling --

MR. KOOPMANN: Sorry.

A -- in my own personal practice until we had the two-year data from the Ward and Hilton study. I knew from previous studies that a randomized compared trial that compared the Burch to the modified Pereyra

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procedure to the modified Kelly-Kennedy plication, that at one to two years the cure rates were similar, but when followed out for three years, that there was a significant drop off of the other two procedures as compared to the Burch. So I would not use the TVT sling until we had that two-year data.

Q (By Mr. Koopmann) Is some evidence thought of as being more powerful than other evidence?

A Yes.

Q What are the highest levels of evidence?

A So the randomized controlled trial is the highest level of evidence. But above that is the meta-analysis, and that is because it's taking multiple randomized controlled trials and putting them together so that you're having a higher number of patients on which to base the conclusions.

Q And what type of evidence did you focus on in evaluating and forming your opinions in this case?

MR. SCHNIEDERS: Object to the form.

A I focused on the meta-analysis, as well as the randomized controlled trials, but primarily looking at the meta-analysis.

Q (By Mr. Koopmann) What is the lowest level of evidence?

MR. SCHNIEDERS: Object to form.

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A The lowest level of evidence, which is considered Level III or Grade C, is the cohort study where patients are followed. And there's the level, like A. So it would be III-A, which would be prospectively followed. And then a lower level than that would be retrospectively.

Q (By Mr. Koopmann) Where do animal studies fall within the levels of evidence?

MR. SCHNIEDERS: Object to the form.

A They do not fall into the evidence for the practice of human medicine.

Q (By Mr. Koopmann) Are levels of evidence important in your opinion in assessing the safety and efficacy of the TVT device?

MR. SCHNIEDERS: Object to form.

A Yes.

Q (By Mr. Koopmann) Why is that?

A Because, again, that's evidence-based medicine. The cohort studies could have those findings by chance, but a randomized compared trial lets you know when you compare to another procedure what the true risks are.

And I'll give an example of that. When we look at the use of hormones in women and we had the retrospective studies, it appeared that there was a

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protective effect for heart disease; but when we followed women prospectively in a randomized controlled trial, we found that that wasn't true.

So looking at the highest level of evidence can provide different information than cohort studies.

Q Are you aware of any device or procedure used to treat stress urinary incontinence for which there is more randomized controlled trial data than the TVT device?

MR. SCHNIEDERS: Object to the form.

A The TVT sling is the best-studied surgery in urogynecology and perhaps of any surgery that's out there, but for sure within urogynecology.

Q (By Mr. Koopmann) And what does that mean for patients? If you were to tell a patient that the TVT is the best-studied device for the treatment of stress incontinence, what does that mean to them?

MR. SCHNIEDERS: Object to the form.

A That the information that we have about the efficacy and the risks are the best type of scientific data that we have, and that this data has been gathered from a very large population of individuals, not only in the United States, but from around the world.

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Q (By Mr. Koopmann) You were asked some questions earlier today about the mesh characteristics for some other manufacturers' mesh devices.
Do you remember that line of questioning?
A Yes.
Q The Perigee product, that's a product that you've used in the past?
A Yes.
Q Is that a polypropylene product?
A Yes.
Q Okay. But that polypropylene is --
(All speaking simultaneously, and reporter requested clarification.)
MR. SCHNIEDERS: Thank you.
Object to form.
Q (By Mr. Koopmann) -- is that polypropylene different from the PROLENE polypropylene that Ethicon uses in its devices --
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) -- their proprietary PROLENE?
A It's going to be different. Same way the mesh for one type of retropubic or transobturator sling is going to be different.

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It's also different in how it is prepared. Like I talked about before, the Perigee product has arms that are attached to the main body of the mesh with little buttons, and the amount of mesh that's placed is much, much greater than what's used with the sling.
Additionally, the amount of mesh that's within the vagina is markedly greater than with the retropubic TVT sling.
Q You were asked some questions earlier about your tracking of the exact numbers of TVT slings or other products that you've implanted in your patients over your career.
Do you remember those questions?
A Yes.
Q And you said that you don't precisely track the exact number of TVT slings or other products you've used; is that fair to say?
A Yes.
MR. SCHNIEDERS: Object to form.
Q (By Mr. Koopmann) Even though you don't track those number precisely, do you still feel comfortable with the estimate of the numbers of slings that you've implanted?
MR. SCHNIEDERS: Object to the form.

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A Very comfortable.
Q (By Mr. Koopmann) And is that something that you discuss with your patients from time to time? If you are recommending that they have a mid-urethral sling to treat their stress incontinence, do you talk to the patient about how many of those slings you've implanted?
A I do.
MR. SCHNIEDERS: Object to form.
Q (By Mr. Koopmann) And --
THE DEPONENT: The court reporter is asking us to slow down and turn a little bit so that she can hear better.
MR. SCHNIEDERS: Sure. Thank you.
Q (By Mr. Koopmann) And do you have an understanding of how some of your colleagues at your current clinic or the clinics you've worked at in the past, how they counseled their patients regarding stress incontinence surgeries?
MR. SCHNIEDERS: Object to the form.
A So they would counsel them very similarly to how I would counsel them regarding the treatment -- surgical treatment of stress incontinence. And as I discussed previously, you know, currently there's three treatments, surgical

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treatments for stress incontinence surgically, and that would be the TVT sling, the pubovaginal sling, and the Burch retropubic urethropexy.
And so, again, we tend to reserve the pubovaginal sling for very complicated cases of stress incontinence, and we would offer either the Burch or the TVT sling; but, again, counseling them that overall, the Burch and the TVT sling have very similar success rates, but because the TVT sling has less -- is less invasive, it has less risks overall.
Q (By Mr. Koopmann) Is it commonplace for surgeons to counsel their patients regarding the number of slings that that surgeon has implanted, even though that surgeon doesn't precisely track the exact number of slings the surgeon has placed?
MR. SCHNIEDERS: Object to the form.
A It should be something that a physician or surgeon discloses to a patient, yes.
Q (By Mr. Koopmann) And as far as you understand, is it commonplace for surgeons to do that for patients, to say, "I've used this sling X number of times," even though that surgeon doesn't have a precise number that's verifiable of the exact number of slings they've placed?
MR. SCHNIEDERS: Object to the form.

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A I don't think it's common for surgeons to say that.
Q (By Mr. Koopmann) You don't think it's common for surgeons to say, "I've put in a thousand TVT slings before," if that's true?
A Oh, if that's true --
MR. SCHNIEDERS: Object to the form.
A -- but I don't --
(All speaking simultaneously, and reporter requested clarification.)
Q (By Mr. Koopmann) -- if that's true, that they have placed a thousand TVT slings.
A No, I think --
MR. SCHNIEDERS: Object to the form. Sorry.
MR. KOOPMANN: He's going to object to every question.
THE DEPONENT: Okay.
MR. KOOPMANN: So just wait two seconds and then give your answer.
THE DEPONENT: Okay.
A So if they've done a lot of slings, I think they will disclose that, and -- but if they've done few slings, I don't think they will disclose that. I don't think they will tend to do that.

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Q (By Mr. Koopmann) When you are discussing with your patients the risks of a midurethral sling surgery like the TVT, do you quote for those patients approximate complication rates that you've seen using the sling in your own practice?
MR. SCHNIEDERS: Object to the form.
A Yes, I do. And oftentimes what I quote to them is the literature; and oftentimes patients will ask me what is my own personal experience, and I will tell them that as well.
Q (By Mr. Koopmann) And do you feel comfortable telling them that?
A I feel --
MR. SCHNIEDERS: Object to the form.
A I feel extremely comfortable in telling them the complication rates because of the very large body of literature that lists those complication rates.
Q (By Mr. Koopmann) And do you feel comfortable telling your patients what your own approximate complication rates are, even though you don't specifically track those complication rates in a data base?
MR. SCHNIEDERS: Object to form.
A Yes, I do for the reasons mentioned, is

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that we're a very small medical community within New Mexico, so it would be unlikely or it would be difficult for a patient to go someplace else outside of Albuquerque.
Q (By Mr. Koopmann) And you were asked some questions earlier about factoring in the pore size of other types of mesh in forming your opinions.
Do you remember that line of questioning?
A Yes.
Q Did you factor in the pore size of the Gore-Tex suburethral slings in forming your opinions regarding the TVT?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) You mentioned -- may I see Exhibit 8, please. It's the whole stack. So let's separate 10 and 11 out there.
A Here's 4. Here it is.
Q Okay.
(Pause.)
Q (By Mr. Koopmann) You were asked some questions earlier today about your awareness of studies that looked at laser-cut mesh versus mechanically cut mesh. And I think you mentioned a study involving the TVT and TVT ABBREVO.

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Do you remember that testimony?
A Yes.
Q In one of your binders here marked TVT Medical Literature Binder 1, there's a study by Dr. de Barros (phonetic) and others.
Is that a study that you reviewed --
A Yes.
Q -- in the course of forming your opinions in this case?
A Yes.
Q And what is the significance of that study?
A So it's the TVT EXACT is laser cut, and the TVT could be mechanical cut or possibly laser cut.
Q So that's a study that looks at TVT laser-cut mesh and the TVT EXACT, and potentially TVT mechanical-cut mesh in the other arm of the study?
A Yes.
Q Another study that's included in your materials is Tommaselli, Abstract Regarding a Comparison of the TVTO and TVT ABBREVO for the Surgical Management of Female Stress Urinary Incontinence; is that correct?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) And the TVT -- well,

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what's the significance of this study?
A Well, the TVTO, again, could either be mechanical or laser cut, and the TVT ABBREVO is laser cut.
Q Okay. Okay. Thank you.
You were asked some questions earlier today about studies that tracked long-term pain.
Do you remember that line of questioning?
A Yes.
Q And is the meta-analysis and systematic review by Dr. Tommaselli and colleagues published in the International Urogynecology Journal in 2015 one of the studies that you've reviewed and relied on in forming your opinions in this case?
A Yes, it is.
Q And in the abstract, it says that the study -- the meta-analysis and systematic review -- looked at studies with a follow-up of 36 months for transobturator midurethral slings and 60 months for retropubic midurethral slings.
That's what was searched for, right?
A Yes.
MR. SCHNIEDERS: Form.
Q (By Mr. Koopmann) And they included data from 49 studies?

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MR. SCHNIEDERS: Object to the form.
A 49 studies were included.
Q (By Mr. Koopmann) If you'll turn to the page containing Table 2.
A Okay. I'm there.
Q Sorry. The continuation of Table 2. It says that they defined as persistent pain all pain reported beyond the perioperative period, meaning greater than seven days after the procedure, correct?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) If you'll look at the next page, they noted that persistent or chronic pain, i.e., pain persisting beyond the perioperative period or reported at the last follow-up visit, was reported by 13 patients for retropubic midurethral slings; is that right?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) And how many retropubic midurethral slings in total were studied in this paper?
A 3,801.
Q Well, that's the number of TVTs, correct?
A Yes.

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Q And how many total retropubic slings in the study?
A 3,974.
Q So 13 patients out of 3,974 had persistent or chronic pain based on this systematic review and meta-analysis?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) Do you have the Schimpf paper? It's at Tab 68.
A Yes.
Q Now, on the first page of the Schimpf paper under Study Design, it indicates that the authors conducted a systematic review, including English language randomized controlled trials for 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling, a Burch urethropexy; is that right?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) And if you'll turn to Table 1, it lists the various studies, the randomized controlled trials that were included in the systematic review, correct?
A Yes.

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Q At the bottom of the first page of Table 1, it lists a couple TVT randomized controlled trials with 12-month follow-up.
MR. SCHNIEDERS: Object to the form.
A There's two with 12-month and one with 48 months. But that's not the TVT.
Q (By Mr. Koopmann) Okay. The TVTs, it says 12 months --
A 12 months.
Q -- for those two?
A Correct.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) And then on the next page of Table 1, it lists many more TVT randomized controlled trials with follow-up duration ranging from 12 months to five years; is that fair to say?
MR. SCHNIEDERS: Object to the form.
A Yes.
MR. SCHNIEDERS: Are you going to ask any nonleading questions, Barry?
Q (By Mr. Koopmann) And if you'll go to the next page, you'll see more TVT randomized controlled trials listed that have a follow-up of 12 months; is that right?
MR. SCHNIEDERS: Object to the form.

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A Yes.
Q (By Mr. Koopmann) And then if you'll turn to Table 3, Table 3 lists the summary estimate of incidents for various complications seen in connection with Burch procedures, retropubic midurethral sling procedures, mini-sling procedures, obturator sling procedures, and pubovaginal sling procedures; is that right?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) And if you'll look at the Exposure section of that table, what does it indicate in terms of the relative risks of retropubic midurethral sling exposure and pubovaginal sling exposure?
A So for the retropubic, it's 1.4 percent with a confidence interval from 1.1 to 1.7 percent.
Q What about for the pubovaginal sling?
A For the pubovaginal slings, it is 5.4 percent with the confidence interval from 4 to 7 percent.
Q Okay. And if you'll go to the next page, it lists, for instance, bowel injury and what the relevance risk for those are with retropubic slings and Burch procedures, correct?

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MR. SCHNIEDERS: Object to the form.
A Can I please mention, because this was something that was brought up --
Q (By Mr. Koopmann) Sure.
A -- in our last discussion.
Return to the operating room for erosion. And that is for the pubovaginal sling, 1.6 percent; and for the retropubic, it is 1.9 percent.
So, again, they are very similar, and it goes back to what I said about all surgeries for stress urinary incontinence have risks.
Q And there's a risk of bowel injury with the Burch procedure?
A Yes.
Q What is that risk according to this study?
A 3.3 percent.
Q And what's the risk of a bowel injury with the retropubic midurethral sling like the TVT, according to this study?
A 0.34 percent.
Q Is a bowel injury a -- potentially a very significant complication?
MR. SCHNIEDERS: Object to the form.
A Yes, it is.
Q (By Mr. Koopmann) Does this table list the

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risk of overactive bladder or urgency?
A Yes.
Q What does it say the summary estimate of incidence for a retropubic midurethral sling procedure --
(Reporter requested clarification.)
Q (By Mr. Koopmann) What does it say the summary estimate of incidence is for overactive bladder or urgency in connection with a retropubic midurethral sling procedure?
A 6 --
MR. SCHNIEDERS: Object to the form.
A 6.9 percent.
Q (By Mr. Koopmann) And what does it say the summary estimate of incidence is for overactive bladder or urgency in connection with a pubovaginal sling procedure?
MR. SCHNIEDERS: Object to the form.
A 8.6 percent.
Q (By Mr. Koopmann) On the next page of Table 3, does it list the summary estimate of incidence for retention lasting longer than six weeks postoperatively?
A Yes.
Q And how does the summary estimate of

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incidence of retention lasting more than six weeks postoperatively compare for retropubic midurethral slings like the TVT and the pubovaginal sling and the Burch procedure.
MR. SCHNIEDERS: Form.
A It's more than twice. Retropubic, 2.7 percent; and the pubovaginal sling and the Burch, approximately 7.5 percent each.
Q (By Mr. Koopmann) And is this study by Dr. Schimpf and colleagues one of the studies that you reviewed and relied upon in forming your opinions in this case?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) This is a systematic review and meta-analysis?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) Like the Tommaselli paper we just went over?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) Do you have the Ford paper in your binder there?
A Yes, I do.

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Q This study was a Cochrane review; is that right?
A It was a -- C-o-c-h -- okay.
Q And it says what their selection criteria were for this paper, correct?
A Yeah, under Search Methods.
Q And then below that it says --
A It says --
(All speaking simultaneously, and reporter requested clarification.)
A Below that it says, Selection Criteria.
Q (By Mr. Koopmann) What does it say under Selection Criteria?
A Randomized or quasi-randomized controlled trials amongst women with SUI, USI, or MUI in which both trial arms involved an MUS operation.
Q MUS operation means mid --
A Midurethral sling.
Q Sorry. You've got to stop and let me finish the question before you start to answer so she can take it all down. All right.
And then the main Result section on the top of the next page, Page 2, does it list there how many trials involving a certain number of women that they included?

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A Yes.
Q What does it say?
A 81 trials that evaluated 12,113 women.
Q And in the author's Conclusions section on Page 2 -- do you see that section?
A Yes.
Q It says there: Midurethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term.
This review illustrates their positive impact on improving the quality of life of women with SUI.
Did I read that correctly?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) And is this one of the studies that you reviewed and relied upon in forming your opinions in this case?
A Yes.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) And is this the type of

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data, along with the Schimpf study we just looked at and the Tommaselli study we just looked at, that you consider to be the highest level of evidence on suburethral slings or midurethral slings?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) If you'll turn to Page 10 of the Ford study, in the right-hand column they talk about Type I mesh; is that right?
A Yes.
Q And what does it say there about Type I mesh?
A Are macroporous and monofilament, and they have the highest biological -- I'm sorry -- highest biocompatibility with the least propensity for infections.
Q And is the TVT mesh and the TVT sling a Type I mesh?
A Yes, it is.
Q And it says further down in that paragraph: Macroporous meshes pore size in excess of 75 microns easily allow macrophages, leukocytes, fibroblasts, blood vessels, and collagen to transverse the pores. Thus, macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of

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infection. Amid 1997.
Monofilament tapes are widely available and now predominate in current clinical practice.
Did I read that correctly?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) And is this information that you reviewed and relied upon in forming your opinion?
A Yes, it --
MR. KOOPMANN: Object to the form.
A Yes, it is.
Q (By Mr. Koopmann) Is the TVT mesh monofilament mesh?
A Yes, it is.
Q You were asked some questions earlier about the terminology of "erosion" versus "exposure."
Do you remember that line of questioning?
A Yes.
Q Has that terminology changed over time?
A It has.
Q Okay. And has your use of that terminology changed over time?
A Yes.
Q Can a suture erosion cause chronic pain?

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MR. SCHNIEDERS: Object to the form.
A In the same way that potentially a mesh exposure could.
Q (By Mr. Koopmann) So the answer is yes?
A Yes.
Q You were asked some questions earlier by plaintiff's counsel about the shrinkage of polypropylene or contraction of polypropylene.
Does scar tissue shrink as it heals?
MR. SCHNIEDERS: Object to the form.
A From an in -- when you make an incision?
Q (By Mr. Koopmann) Yeah.
MR. SCHNIEDERS: Object to the form.
A So there will be some minor shrinkage, and then there may be actually some stretching out with time as the tissues get remodeled.
Q (By Mr. Koopmann) And so if there is any shrinkage of a sling following the implantation of the TVT, is it the mesh itself that shrinks, or is it the tissue that's incorporated into the mesh that shrinks?
MR. SCHNIEDERS: Object to the form.
A More than likely it's the tissue that's growing into the mesh.
Q (By Mr. Koopmann) You were asked some

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questions earlier about whether the mesh -- the TVT mesh was designed to do certain things like rope or curl or fray or lose particles.
Do you remember those questions?
A Yes.
Q And I think your testimony was: It's designed to correct SUI, correct?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) For instance, a car could be driven into a ditch, but it wasn't necessarily designed to do that; is that fair to say?
MR. SCHNIEDERS: Object to the form.
A Yes.
Q (By Mr. Koopmann) Do you think surgeons need to be informed by medical device manufacturers about risks that are commonly known among pelvic floor surgeons?
MR. SCHNIEDERS: Object to the form.
A No, I do not.
Q (By Mr. Koopmann) You were asked some questions earlier about whether a 30 percent shrinkage rate would need to be passed along.
What sort of data do you think would be required in your opinion for a 30 percent shrinkage

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rate to be passed along?
Would it need to be -- you know, could it be a single case report or would it need to be randomized controlled trials or what sort of evidence would you want to be seeing there?
MR. SCHNIEDERS: Object to the form.
A So as I mentioned previously, for there -- there would have to be evidence of shrinkage clinically. And that could be done in multiple, multiple studies; and that could be done with ultrasound; it could be done with examination, for example, with a Q-tip test where if there was that amount of shrinkage, then we should see contraction underneath the urethra.
So we mention the Q-tip test, that means the Q-tip test would be negative, so it would be deflected downward, indicating that the urethra was being pulled up.
We would also see significant increase in voiding dysfunction or otherwise known as urinary tension with the shrinkage.
And as we just reviewed the Schimpf article, the risk of retention with the retropubic TVT sling is quite low, and surgical revision of the TVT sling for retention is also very low and doesn't

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increase with time.
So this clinical data supports that the TVT does not shrink with time. And so for that to be refuted would require extensive studies.
Q (By Mr. Koopmann) Okay. If there's a document in the binder that's labeled SUI Mesh Documents Binder 1 that references a 30 percent rate of shrinkage of the TVT sling, is that a document that you would have reviewed before forming your opinions in this case?
A Yes, it is.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) Because you've reviewed all the documents in SUI Mesh Documents Binder 1?
MR. SCHNIEDERS: Object to the form.
(Reporter requested clarification.)
Q (By Mr. Koopmann) Is that because you've reviewed all of the documents in SUI Mesh Documents Binder 1?
MR. SCHNIEDERS: Object to the form.
A Yes, I reviewed all of those documents.
Q (By Mr. Koopmann) You were asked some questions earlier about some Code of Federal Regulations -- regulations and FDA guidance documents that you reviewed.

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Do you remember those questions?
MR. SCHNIEDERS: Object to the form.
A Yes, I do.
Q (By Mr. Koopmann) Is it fair to say that what you reviewed in those documents is consistent with your opinions regarding the appropriateness of the IFU that you set forth in your general TVT expert report?
MR. SCHNIEDERS: Object to the form.
A Yes. As I said in my report is that it's really dependent on the surgeon to know what the risks are for any given procedure, and that the IFU should contain only those things that are not well known to a surgeon or those things that are specific to that device. And that is consistent with what I wrote in my general report.
Q (By Mr. Koopmann) You were asked some questions about a paper by a Dr. Gerard Agnew and others entitled Functional Outcomes Following Surgical Management of Pain Exposure or Extrusion Following a Suburethral Tape Insertion for Urinary Stress Incontinence.
Do you remember those questions?
A Yes.
Q If that article was published in the

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International Urogynecology Journal in 2014, do you think it's more likely than not that you would have reviewed that particular paper when it was published?
MR. SCHNIEDERS: Object to the form.
A Absolutely.
Q (By Mr. Koopmann) Because you read the International Urogynecology Journal every month or whenever it comes out?
A Yes.
MR. SCHNIEDERS: Object to the form.
A Yes, I do, along with the journal from AUGS.
Q (By Mr. Koopmann) Has all of the journal reading that you've been doing on stress incontinence and its surgical treatment over the course of your career been factored into your opinions that you formed in this case?
A Yes --
MR. SCHNIEDERS: Object to the form.
A Yes, it has.
Q (By Mr. Koopmann) And based on your use of the TVT device in more than a thousand surgical cases and your review of the medical literature regarding the TVT sling and alternative treatments, do you consider yourself an expert on the design of the TVT

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sling?
MR. SCHNIEDERS: Object to the form.
A Yes, I do.
Q (By Mr. Koopmann) There's no manufacturer to teach surgeons how to tension the sutures used in a Burch procedure, is there?
MR. SCHNIEDERS: Object to the form.
A No, there is not. That's something that you learn during your training and that you learn while operating on patients.
Q (By Mr. Koopmann) There's no manufacturer to teach surgeons how to properly tension an autologous fascial sling, is there?
MR. SCHNIEDERS: Object to the form.
A No, there is not.
Q (By Mr. Koopmann) Does the amount of mesh used in a sling procedure depend to some extent on the patient's body habitus?
MR. SCHNIEDERS: Object to the form.
A So the more heavy a patient is, the more subcutaneous tissue there is, the greater the mesh that will be used, although, the amount that's within the vaginal area will be pretty much the same because it's the subcutaneous tissues that are abdominally where the increased length of the sling will be.

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(Pause.)
Q (By Mr. Koopmann) Does the reliable scientific evidence that you have assessed on the TVT device and the intended use of treating stress urinary incontinence show that there's a significant risk of mesh roping?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Does it show that there's a significant risk of mesh curling?
A No.
MR. SCHNIEDERS: Object to the form.
Q (By Mr. Koopmann) Does it show that there's a significant risk of mesh fraying?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Does it show that there's a significant risk of mesh pore collapse?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Does it show that there's a significant risk of degradation?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Does it show that

there's a significant risk of fibrotic bridging?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Does it show that there's a lack of biocompatibility for the TVT mesh?
MR. SCHNIEDERS: Object to the form.
A No.
Q (By Mr. Koopmann) Have all of the opinions that you've offered here today been offered to a reasonable degree of medical certainty?
A Yes, they have.
MR. KOOPMANN: Those are all the questions I have.
MR. SCHNIEDERS: All right. It's 1:15 your guys' time, so why don't we plan on coming back in at 2:00 your time, all right?
MR. KOOPMANN: Okay. That sounds good.
(The deposition concluded at 1:15 p.m., March 7, 2017.)

I, DOROTHY KAMMERER-DOAK, M.D. do hereby certify that I have read the foregoing transcript and that the same and accompanying amendment sheets, if any, constitute a true and complete record of my testimony.

_____
Signature of Deponent
( ) No amendments
( ) Amendments attached

Acknowledged before me this _____ day of _____, 20__.

Notary public:
_____

My commission expires:
_____
Seal:

DLB

STATE OF COLORADO)
) ss. REPORTER'S CERTIFICATE
COUNTY OF DENVER)

I, Dianna L. Buckstein, do hereby certify that I am a Professional Shorthand Reporter and Notary Public within the State of Colorado; that previous to the commencement of the examination, the deponent was duly sworn to testify to the truth.

I further certify that this deposition was taken in shorthand by me at the time and place herein set forth, that it was thereafter reduced to typewritten form, and that the foregoing constitutes a true and correct transcript.

I further certify that I am not related to, employed by, nor of counsel for any of the parties or attorneys herein, nor otherwise interested in the result of the within action.

In witness whereof, I have affixed my signature this 20th day of March, 2017.

My commission expires November 25, 2017.

_____
Dianna L. Buckstein
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